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Morehouse School of Medicine
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MANAGING MULTIPLE RISK FACTORS FOR CARDIOVASCULAR DISEASE

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Scientific Report

This report details the background and significance, methodology, statistical results and discussion of research findings for this clinical trial. This report was prepared using APA publication standards.

INTRODUCTION

Despite the decrease in coronary heart disease mortality over the past 30 years, coronary heart disease (CHD) continues to reign as the leading cause of death in men and women. Cardiovascular disease, including CHD, kills nearly 500,000 American women each year and black women generally have a higher prevalence of CHD risk factors and a higher death rate at a younger age than white women (Haan, 1996). Risk factors are highly prevalent in women aged 20-74 years. One third have hypertension, ¼ have hypercholesterolemia, ¼ are overweight, and ¼ are sedentary. These factors are more prevalent in women of lower socioeconomic status and lower educational level (Wenger, 1995). In 1995, an estimated 34.3% of women reported having 1 risk factor and 30% of women reported having two or more of the following risk factors for cardiovascular disease: hypertension, high blood cholesterol, diabetes, overweight and smoking. The prevalence of two or more risk factors increased with age, decreased with educational level and was higher among black women. The percentage of women with two or more risk factors was significantly higher than estimates from 1992 (Greenlund, et al., 1998).

Consistent with these findings, Poduri & Girsso (1998) found that the mean number of cardiovascular risk factors among low income women was 2.6 and that knowledge and understanding of these risk factors was suboptimal, particularly among women personally affected by risk factors for CVD. Most of these risk factors tended to be higher among ethnic minority women than white women. After adjusting for education there were significant differences in blood pressure, BMI, physical inactivity and diabetes in blacks as compared to whites. After controlling for income and education, African-American women were twice as likely as Caucasian women to report risk factors of obesity and sedentary lifestyle. Moreover, women from lower SES had a significantly higher prevalence of smoking and physical inactivity and higher levels of BMI and non-HDL-C than women of higher SES (Winkleby, Kraemer, Ahn, & Varady (1998; Harrell & Gore, 1998). With respect to dietary risk factors, investigators have documented greater consumption of cholesterol and less consumption of potassium in African-American women. Dietary magnesium is also lower in African-Americans. Moreover, magnesium levels are significantly lower in those with prevalent cardiovascular disease, hypertension and diabetes than in those without these diseases (Folsom, et al., 1995; Gates & McDonald, 1997).

Hypertension is one of the single most important risk factors for cardiovascular disease and the prevalence of this disease is greater, appears at an earlier age and is more likely to be associated with end-organ damage in African-Americans (Lackland, & Keil, 1996). Although obesity has been shown to be highly related to cardiovascular risk (Stolley & Fitzgibbon, 1997), the positive association between obesity and blood pressure has been less consistent in African-Americans than whites. Nonetheless, researchers have documented that BMI is positively and independently associated with changes in blood pressure after controlling for weight change and other covariates. Baseline weight and weight gain among those who were initially normal weight were independent predictors of blood pressure increase for African-Americans in the Pitt County Study of hypertension (Curtis, Strogatz, James & Raghunathan, 1998). Body mass index and African-American race are associated with higher blood pressure with and without drug therapy (Kumanyika et al.,1998). Other research has shown that waist circumference is positively correlated with blood pressure and that waist circumference correlates better with visceral adipose tissue and is a better predictor of cardiovascular

disease than are BMI and waist to hip ratio (Okosun et al., 1998). The Coronary Artery Risk Development in Young Adults (CARDIA) study documented a positive association of hypertension with age, body mass index, and alcohol intake and a negative association with physical activity, cigarette use and intake of potassium and protein (Liu et al., 1995).

Although less understood and more difficult to quantify, there have been direct associations between psychosocial stress and blood pressure in African-Americans. Some theoretical models argue that African-Americans are engaged in a chronic struggle to achieve and maintain valued social and personal goals in the context of few socioeconomic resources. This struggle is postulated to be associated with high blood pressure and as contributing to the greater experience of frustration and anger that compounds blood pressure elevation (Dressler, 1996). Emotional support and instrumental support tends to buffer the relationship between stress and blood pressure (Strogatz et al., 1997). Some investigators have shown laboratory analogs of stressful situations have elicited increases in blood pressure (Morris et al., 1996). Work-related stress has been associated with an increased risk of hypertension and more severe cardiovascular problems. In African-Americans high-effort coping plus high job status is associated with high work and laboratory diastolic pressure and higher work systolic pressure (Light et al., 1995). High anxiety and high depression have been shown to be independent predictors of incident hypertension in some research (Jonas, Franks & Ingram). Socioeconomic, educational and lifestyle stressors appear to converge and result in increased sympathetic drive and augmented neurovascular tone. The heightened sympathetic drive as well as the increased vascular reactivity emerge as major contributors to the risk factor cluster in African-American women. Patterns of comorbidity and mortality risk in blacks and whites clearly show that an excess burden of chronic disease in black women as compared to white women (McGee, Cooper, Liao & Durazo-Arvizu (1996). These findings justify targeting women at high risk for cardiovascular disease as one approach for reducing the excess cardiovascular morbidity and mortality among African-American women.

It is well accepted that the standard drug treatment for hypertension often causes adverse side effects that reduce quality of life and is believed to be a causal factor in non-compliance with prescribed anti-hypertensive regimens among blacks and whites (Kaplan, 1990). Despite the fact that anti-hypertensive drug therapy is quite effective in reducing cardiovascular morbidity in blacks, it has been estimated that more than two-thirds of patients are non-compliant with medical regimens. The U.S. Joint National Committee on the Detection, Evaluation and Treatment of High Blood Pressure (JNC, 1997) recommended the use of lifestyle modification therapies as a first line of treatment of mild hypertension and as an adjunctive treatment for stage 2 and 3 hypertension. Although the JNC does not recognize stress reduction therapies as a definitive treatment for hypertension due to the paucity of randomized controlled studies in this area, there is evidence that behavioral interventions such as meditation and progressive muscle relaxation are effective in lowering blood pressure. A number of studies have shown that meditation is more effective than other stress reduction methods in lowering blood pressure.

In one randomized trial of stress reduction therapies conducted by Schneider and associates (Schneider et al., 1992), the effectiveness of transcendental meditation was compared to progressive muscle relaxation as well as the usual non-drug care (diet and exercise) for managing hypertension in elderly African-Americans. Results indicated that after 3 months of follow-up, TM and PMR showed significant blood

pressure reductions compared to the usual care. The significantly greater reductions in the TM group (13/7 mmHg) were of the same order of magnitude as the average blood pressure reductions with drug therapy reported for most clinical trials of mild hypertension (Kaplan, 1990). This study focused on older African-Americans (age 55 and older) and demonstrated significant reductions in clinic and home blood pressure compared with other groups. There is a need to determine whether meditation will be equally effective in younger African-American women and if it will be effective in modifying additional cardiovascular risk factors besides blood pressure.

Reduction of blood pressure in hypertensive patients is an important objective, since pressure-related complications such as stroke, heart failure, and renal insufficiency and failure are significantly reduced or delayed. However, cardiovascular risk factors often cluster which may explain why lowering blood pressure alone does not achieve the expected risk reduction in atherosclerotic events including coronary heart disease. Since meditation appears to reduce the stress and associated increase in sympathetic nervous system activation which contribute to the risk factor cluster, meditation may be effective not only in reducing blood pressure, but other components of the risk factor cluster and angry/hostile responses to stress. The effects of meditation on the risk factor cluster have not been examined in African-Americans. One of the few studies which examined the relationship between meditation on cardiovascular risk factor profile revealed a reduction in blood pressure and other risk factors (smoking, drinking and cholesterol) among long term meditators over a 5 year period (Orme-Johnson, 1987). However, this study was not a randomized clinical trial so causality could not be ascertained. The current research proposed to examine the interrelationships between anger/hostility and both cardiovascular and psychological risk factors for African-American women. We also determined if a program of meditation could lower the composite score for risk factor clusters, reactivity to stress and improve family/job stress and work performance more effectively than lifestyle changes alone for African-American women with multiple risk factors for cardiovascular disease.

Specific Aims and Hypotheses for Baseline Measures: Determine the interrelationship between anger/hostility and both cardiovascular and psychological risk factors for African-American women.

Hypothesis 1: Anger/hostility will be positively correlated with blood pressure, lipids, plasma catecholamines and body fat.

Hypothesis 2: Anger/hostility will be positively correlated with negative health practices such as smoking, drinking and sedentary lifestyle.

Hypothesis 3: Anger/hostility will be positively correlated with family and job stress, anxiety and depression.

Hypothesis 4: Anger/hostility will be negatively associated with job performance, productivity at work, relationships with co-workers and supervisors.

Specific Aims and Hypotheses for the Intervention: Determine if transcendental meditation lowers the composite score for risk factor clusters, reactivity to stress and improves reported family/job stress and work performance more effectively than lifestyle

change alone for African-American women with multiple risk factors for cardiovascular disease.

Hypothesis 1: Transcendental meditation will reduce the risk factor cluster more effectively than lifestyle changes alone by lowering sympathetic drive and vascular reactivity.

Hypothesis 2: Transcendental meditation will reduce psychological stress (i.e. anxiety, anger, depression), lipids and physiological responses associated with laboratory induced stress.

Hypothesis 3: Women who received training in transcendental meditation will report better relationships with coworkers and supervisors, perform more efficiently and effectively on their jobs and report less stress during the follow-up phase.

METHOD

Subjects & Design

This study was a randomized, single blind, controlled study of transcendental meditation versus an intensive lifestyle educational program. It was conducted with 124 African-American women ages 18-70 years. These women had high normal blood pressure to mild hypertension (i.e. blood pressures within the range of 130/85-159/104 were accepted for inclusion) and at least 2 additional self reported risk factors for cardiovascular disease (i.e. family history of hypertension, overweight, high cholesterol, smoking, drinking, high sodium intake, sedentary lifestyle).

The risk factor cluster computed for this study included overweight/obesity as measured by BMI, hypertension, physical inactivity, excessive alcohol intake, smoking and added sodium to diet. Women who were identified as having any of these risk factors were given a score of one while women who did not report the risk factor were given a score of zero. Therefore, the range of scores for the risk factor cluster were 0-6. All women had baseline assessments of cardiovascular disease risk factors (hypertension, hyperinsulinemia, overweight/obesity, body fat distribution, dyslipidemia, dietary sodium intake) and psychosocial (anger/hostility, anxiety, depression, family/job stress, stress coping styles, smoking, drinking, sedentary lifestyle) risk factors. These women were randomly assigned to either the meditation or lifestyle education group.

The following women were excluded from the study: Women greater than 70 years old, taking more than 4 antihypertensive medications, using insulin, manifesting renal insufficiency, evidence of previous myocardial infarction, with history of accelerated or malignant hypertension, diabetes, cerebrovascular accident, unstable angina, congestive heart failure, evidence of major psychiatric illness, alcohol or drug abuse or pregnancy.

Subjects were recruited from community health screenings and through public advertisement. We obtained the following information from study participants: body fat measurement, fasting lipoprotein profile, blood pressure/hypertension history, physical activity habits, alcohol consumption, cigarette smoking, job/family stress, job satisfaction, coping styles, life stress information.

The diagnosis of high normal blood pressure to mild hypertension is based upon blood pressure measurements taken during a 3-week baseline clinic measurements. Casual (seated) blood pressure was obtained in triplicate on the right arm supported at heart level after the participant has rested for five minutes. Phase 5 Korotkoff defined diastolic blood pressure and the two closest blood pressure readings were averaged. Only volunteers with blood pressures consistently in the 130/85-159/104 mmHg range over a 3-week period consisting of 3 blood pressure readings were eligible.

The single blind was maintained by having research staff who obtained the blood pressure and physiological data remain unaware of the participants intervention status. The two groups received equal amounts of professional contact time.

Intervention and Control Group

Each of the active treatments were introduced in ways that encouraged some degree of expectancy and benefits for the prevention of disease and promotion of health. Prior to participation in the interventions, participants completed a questionnaire about their expectations regarding the treatment and their perceptions of the

interventions effectiveness for managing their blood pressure. The transcendental meditation and lifestyle education programs were taught with similar formats, amount of instructional time, professional attention from the instructor and daily practice time. The general format of instruction in the active treatment was modeled after the standard transcendental meditation training course. This includes an introductory lecture meeting, which is done in a group format to discuss benefits and mechanisms of the technique, a brief personal interview, a session of personal instruction and follow-ups in group meetings. These initial steps consisted of 5 meetings which took place over 4 consecutive days and lasted about 1 hour per day. At the end of this period, the groups met once every other week for roughly 11/2 hours for a total of 8 follow-up visits. The meditation technique is a simple mental procedure, practiced twice a day for 20 minutes while sitting with eyes closed. During the technique the ordinary thinking process settles down and a distinctive psychophysiological state of restful alertness appears to be gained.

The lifestyle educational participants received instruction for modifying the major risk factors with conventional behavioral approaches. Participants received the same number of sessions as participants in the active intervention condition. Participants learned about the importance of diet, salt, weight control or management, exercise and the effects of these factors on controlling blood pressure. The group sessions included information on smoking cessation and promotion of physical activity. The participants also covered the topic of stress in a didactic format, but no specific instruction in stress reduction or relaxation techniques was given. Participants in both the meditation and lifestyle education groups were requested to complete compliance forms to monitor their respective practice/implementation of meditation and lifestyle changes.

Measures

The following is a description of the measures that were obtained from participants:

Overweight is defined as a body mass index (BMI) 25-27 kg/m2 and obesity is defined as BMI 27-40 kg/m2 or greater. Defining obesity by BMI does not distinguish between overweight and overfat. Thus, body fat is estimated.

Plasma catecholamines and plasma renin activity was measured through Associated Medical Laboratories.

Dyslipidemias are determined via measurement of a fasting lipoprotein profile including total cholesterol, triglycerides, HDL, LDL, VLDL cholesterol. Hypercholesterolemia is defined according to National Cholesterol Education Program guidelines. Since many hypertensive patients have additional risk factors such as obesity and cigarette smoking, total cholesterol > 200 mg/da and LDL cholesterol >130 mg/dl are abnormal. Based on evidence from Framingham and other sources, triglycerides >150 mg/dl, particularly in association with HDL-C < 40 for women and <35 mg/dl for men are abnormal. These measure were determined by Associated Medical Laboratories.

Physical activity, alcohol consumption and cigarette smoking are lifestyle variables which were assessed with a questionnaire modeled after the **MRFIT** instrument.

Compliance and expectancy was defined according to methods suggested by Jacobs and Chesney. Participants recorded their daily practice of meditation or lifestyle changes on a log sheet for the week. An indirect but objective indicator of compliance is the attendance at the follow up meetings. Attendance records were kept by the meditation and lifestyle instructors.

Psychosocial Questionnaires assessed a number of dimensions associated with life stress, coping, health behaviors. The following is a description of the primary dimensions assessed & questionnaires:

Health Behaviors: This questionnaire assessed substance use, smoking, drinking, diet, exercise and rest/relaxation. It has been utilized other research trials assessing the impact of meditation on high blood pressure.

SCL-90-R: A multidimensional symptom self-report inventory comprised of 90 items each measured on a 5-point scale of distress from "not at all" to "extremely". The SCL-90 quantifies psychopathology in terms of 9 primary symptom constructs: somatization, obsessive compulsice, interpersonal sensitivity, depression, anxiety, hostility, phobic anxiety, paranoid ideation, and psychoticism. In addition, three global measures reflet distinct aspects of overall psychological distress. Alpha coefficients of reliability range from .77 for the psychoticism dimension to .90 for depression (Derogatis, Rickels & Rock, 1976).

Perceived Stress Home/Work Scales: These items assess the frequency with which individuals felt a sense of control over situations occurring in home and work environments. The scales are comprised of 14 items each measured on a 5-point frequency scale from "never" to "very often. The alpha reliability for these scales was .83 (PSH) and .72(PSW).

Job Satisfaction/Performance: Fourteen items were developed to assess self-reported job satisfaction, indicators of performance (i.e. past job reviews, absences, sick leave, etc.) and relationships with co-workers.

Social Support: Items from the National Survey of Black Adults were utilized to assess tangible and intangible social support.

The State-Trait Anxiety Inventory : This scale consists of 44 items which form five primary scales and two subscales. It provides a brief objectively scored measure of the experience, expression and control of anger (Spielberger, 1988). This scale measures the intensity of anger as an emotional state (state anger) and the disposition to experience angry feelings as a personality trait (trait anger). Frequency of anger expression is assessed by 3 subscales: anger-out, anger-in and anger-control.

Cook-Medley Hostility: This self-report scale measured the attitude and personality trait of hostility (Cook and Medley, 1954) which has been found to be predictive of heart disease and cardiovascular risk factors for heart disease (see Williams, 1989).

Procedure

One hundred twenty four African-American women participants were enrolled into the study. These women completed the first phase 3-week baseline assessment of blood pressure to confirm eligibility, medical history and cardiovascular reactivity stress test and blood draw. Casual (seated) blood pressure was obtained in triplicate on the right arm supported at heart level after the participant has rested for five minutes. Phase 5 Korotkoff defined diastolic blood pressure and the two closest systolic blood pressure readings will be average. Only volunteers with blood pressures consistently in the 130/85-159/104 mmHg range over a 3-week period consisting of 3 blood pressure readings were deemed eligible. At their 2nd blood pressure assessment, patients completed a medical interview questionnaire packet which assessed health behaviors, coping, anger/hostility, etc. At their 3rd visit to the clinic, following their 3rd blood pressure assessment, participants underwent a cardiovascular reactivity test and 24-hour ambulatory blood pressure monitoring. The tests used represented a range of autonomic stressors from relatively selective beta-adrenergic stressors (mental

arithmetic) to relatively selective alpha-adrenergic stressors (forehead cold pressor). Participants systemic hemodynamic (blood pressure, heart rate) response was obtained at 2 minute intervals in those tests or recovery periods lasting more than 4 minutes. The following depicts the tasks utilized in the reactivity protocol.

a. Resting baseline (sit quietly for 5 minutes then start 10 minute baseline)
b. Arithmetic test (6 minutes)
c. Rest and recovery (3 minutes)
d. Fore head cold pressor test (90 seconds)
e. Rest and recovery (3 minutes)
f. Stress interview (10 minutes)
g. Rest and recovery (20 minutes)

In addition to the reactivity protocol, all patients had their weight and height measured using a standardized physician's weight scale and height measurement attachment. Subjects underwent a blood draw so that blood chemistry profiles assessing lipids and catecholamines could be measured. During phase two, patients were randomly assigned to either receive lifestyle modification or transcendental meditation. Within a month of assignment patients began their intervention groups which involved 13 visits to the clinic for 1 ½ hour sessions. These visit occurred consecutively for the health education group and occurred bimonthly for the TM group after the first 5 consecutive steps in the TM training. Despite the slight variation in format, both groups received the same amount of time and attention from interventionists and occurred within the same time frame. Following the completion of the intervention all participants completed a follow-up assessment which involves completing an post-test medical history questionnaire and a follow-up cardiovascular reactivity test and ambulatory blood pressure monitoring and blood draw. Seventy four participants completed phase two. Phase three of the project involves patients returning for a six-month follow-up medical history questionnaire and cardiovascular reactivity test. Thirty-nine participants completed the final phase of the study.

RESULTS

Baseline demographic characteristics of the women enrolled in this project follow:

Table 1: Demographic and Cardiovascular Risk Behaviors

Age	*51.4 ± 10.3 years*
Married	*46.6%*
College/Advanced Educ.	*69.6*
Income>$20,000	*44.4%*
Taking medication for Hypertension	*68.6%*
Smoke	*10.1%*
Add Salt to Diet	*73.7%*
Overweight	*87.9%*
Physical Inactivity	*69.4%*
Family History of CVD	*84.7%*

The following reflect the results of baseline analyses. Pearson correlations were conducted to examine these hypotheses. Anger was assessed using the subscales of the State Trait Anger Expression Inventory (STAXI) (anger out, anger in, anger control, state anger, trait anger) and the subscales of the Cook-Medley Hostility Questionnaire (cynisism, hostile affect, aggressive response)

Hypothesis 1: Anger/hostility will be positively correlated with blood pressure, lipids, plasma catecholamines and body fat.

- Anger-Out, the tendency to express anger without reflection or control was negatively associated with diastolic blood pressure, r= -.20, p<.05.
- State anger, the tendency to respond to situational based experiences with anger, was negatively associated with total cholesterol, r=-.24, p< .05.
- Triglyceride levels were associated with greater aggressive responding on the Cook Medley, r=.28, p<.05. There were no associations found between anger and catecholamine levels or anger and body fat.

Hypothesis 2: Anger/hostility will be positively correlated with negative health practices such as smoking, drinking and sedentary lifestyle.

- There was a positive association found between cynicism and physical activity, r=.23, p<.05.
- There was also a positive association found between hostility and alcohol consumption, r=.27, p<.01.

Hypothesis 3: Anger/hostility will be positively correlated with family and job stress, anxiety and depression.

Positive associations were found between the following variables:

- State anger and depression (r=.43, p<.001) and anxiety (r=.43, p<.001).
- Trait anger and depression (r=.36, p<.001) and anxiety (r=.35, p<.001)
- Anger in and depression (r=.44, p<.001); anxiety (r=.45, p<.001); perceived stress at home (PSH)(r=.28, p<.01); and perceived stress at work (PSW) (r=.24, p<.05).
- Anger out and depression (r=.19, p<.05); anxiety (r=.21, p<.05); PSH (r=.22, p<.05)
- Cynicism and depression (r=.41, p<.001); anxiety (r=.37, p<.001); PSH (r=.30, p<.01)
- Hostile affect and depression (r=.27, p≤ .005) and anxiety (r=.19, p<.05)
- Aggressive responding and depression (r=.22, p<.05); anxiety (r=.36, p<.001); PSH (r=.26, p<.01).
- Hostile affect and PSH, r=.26, p<.01 and PSW, r=.34, p<.01.
- Negative associations were found between anger control and PSH, r=-.31, p<.01 and PSW, r= -.33, p<.01)

Hypothesis 4: Anger/hostility will be negatively associated with job performance, productivity at work, relationships with co-workers and supervisors.

- There were no associations found between anger/hostility and self-reported job performance, satisfaction or work relationships.

The following reflect the findings of analyses for the intervention hypotheses.

Hypothesis 1: Transcendental meditation will reduce the risk factor cluster more effectively than lifestyle changes alone by lowering sympathetic drive and vascular reactivity.

- This hypothesis was not supported by the data at immediate or 3-month follow up. Among individual risk indicators, there were no significant differences found for BMI, number of cigarettes smoked daily, amount alcohol consumption weekly or frequency of exercise at immediate or 3-month follow-up.

Hypothesis 2: Transcendental meditation will reduce psychological stress (i.e. anxiety, anger, depression), lipids and physiological responses associated with laboratory induced stress and field stress as measured by ambulatory blood pressure monitoring.

- There were no between group differences in psychosocial stress at immediate or 3-month follow up, with the exception of anger control. At 3-month follow up, this factor was significantly higher in those who had been previously exposed to HE; $F(1,30)=5.5$, $p<.05$. Mean TM anger control subscale score=22.3±4.1 and the mean HE anger control subscale score=25.7 ± 3.6.
- Following intervention, women who received meditation had lower HDL levels than women who were in the lifestyle modification counseling group, $F(1,36)=4.3$, $p<.05$. Mean HDL levels TM=57.4 ± 23.7; Mean HDL levels HE=70.1± 22.9. Lipid levels were not assessed at 3-month follow up. Follow up diastolic blood pressure was higher in the TM group, $F(1,65)=5.3$, $p<.05$. Mean TM DBP=88 ± 8.1 mmHg while the HE SBP=83 ± 7.1 mmHg. These differences were not sustained at 3-month follow-up. There were no differences found for reactivity to stress at immediate or 3-month follow up. There were also no differences found in 24-hour ambulatory systolic and diastolic blood pressure.

Hypothesis 3: Women who received training in transcendental meditation will report better relationships with coworkers and supervisors, perform more efficiently and effectively on their jobs and report less stress during the follow-up phase.

- This hypothesis was not supported at immediate or 3-month follow up.

DISCUSSION

Although this clinical trial did not support our primary intervention hypotheses there were some notable findings revealed from this clinical trial. At baseline, we found negative associations between blood pressure and the tendency to express anger without

reflection as well as between situation anger (state anger) and total cholesterol. These findings suggest that anger that is expressed rather than held in as well as anger that is non-characterological may have less aversive effects on sympathetic nervous system activation. Consequently, the sequelae of physiological responses related to activation of this system such as increased production of lipids may be prevented by not suppressing emotional responses. Contrarily, we found that aggressive attitudes which tend to be more characterological in nature as measured by the Cook-Medley hostility questionnaire was related to increased levels of triglycerides. These findings have important implications for the role of personality and health. Clearly, individuals who have more aggressive personality styles could benefit from cognitive-reframing such that their more characterological attitudes would have less aversive effect on their health.

With respect to psychosocial functioning, we found significant interrelationships between anger and hostility and depression, anxiety, and perceived stress. Negative associations were found between anger control (the tendency to express anger with reflection) and perceived stress at home and work. Apparently, individuals who are able to manage their anger and express it in a calm, yet assertive manner perceive their environments as less stressful. Those who either keep their anger in or vent may feel that they lack control over their environments and as a result feel more stressed.

Our intervention hypothesis that transcendental meditation (TM) would reduce the risk factor cluster more effectively than lifestyle modification was not supported. Interestingly enough, with respect to physiological variables, the lifestyle modification program had more protective effects. Those women who learned TM had lower HDL levels than women who received health education via the lifestyle modification group. Also, the follow-up diastolic blood pressure was higher in the TM group as compared to the lifestyle modification group. These differences were not sustained at 3-month follow-up. It appears that our educational control had the effects of an active intervention and that women in this group may have actively applied the information they received to change their diets. These differences may reflect the impact of nutritional changes on the physiology rather than be an effect of lowering sympathetic nervous system activation. Although we did not find any significant differences in psychosocial stress between the two groups at immediate follow-up, our study did reveal significant increases in anger control for those women who learned HE at 3-month follow up than those in the lifestyle modification group. It may be possible that although the women in this group did not learn specific stress reduction techniques they felt more empowered following intervention and over time developed more effective coping responses. We were unable to determine the later in that lipid levels were not assessed at the 3-month short-term follow up period. The fact that blood pressure differences were not sustained may be indicative of the women not sustaining lifestyle changes or indicative of the TM becoming more effective at 6 months of practice. These findings support the need for more research on the longer term effects of TM.

Other interesting findings in this study that were not related to our hypotheses were revealed. We found that within the lifestyle modification group, both systolic and diastolic blood pressures were reduced following intervention. Systolic blood pressure was reduced by 8 mmHg while diastolic blood pressure was reduced by 6 mmHg. Individuals who were previously categorized at the Stage I hypertension levels became controlled to the High Normal level. In addition, perceived stress at home was significantly lower in this group at follow-up. Although this intervention group did not have a stress reduction technique taught, it apparently had stress reducing qualities

which may have been associated with having a support group to attend. Also, the fact that individuals may have felt better physically may have reduced their perceptions of stress. In the TM group, systolic blood pressure was lowered by 4 mmHg and state anger as well as perceived stress at home was significantly reduced. Interestingly enough, the risk cluster increased from baseline to follow up. It is possible that individuals who learned to use TM as a coping strategy for reducing blood pressure may have become less conscious of using other lifestyle modifications (i.e. diet and nutrition) to control their condition. These findings have important implications for the use of conjoint therapies (i.e. TM and Health Education) to control hypertension.

In conclusion, although the HE intervention was an educational control, it is possible that the group dynamics and information presented to participants had stress reducing components via the empowering them to feel more control over their lives and engage in more adaptive coping. And clearly both TM and HE interventions have some efficacy for managing hypertension. Nonetheless, there are a number of limitations that must be addressed in future research. The lack of between group findings for many of the primary hypotheses could suggest that a placebo effect is responsible for the reductions in blood pressure. Alternatively, it is possible that the time and attention control has stress reducing properties, which could have prevented the HE group from being an adequate "usual care" control group or the time and attention control truly had intervention components affecting another mechanism besides stress for reducing blood pressure. It is also conceivable that differences were not found due to the amount of time TM was practiced. It is possible that 3-months of supervised practice was not significant enough time period to see effects. Future research should address the need for adequate control groups. Moreover, although HE is likened to the usual care, it is far more intensive than usual care provided in clinical settings. Future studies should examine the role of group health education versus that conducted in physician's offices or provided to patients via informational literature. Finally, future research needs to be done which addresses the longer-term effects of behavioral interventions and the additive effectiveness of conjoint behavioral interventions.

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This bibliography details all abstracts, national/international presentations and publications generated using data from this clinical trial. It also details personnel, both faculty/staff and consultants, who worked on the contract during various periods and were paid using contract funds.

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Cardiovascular Disease

Abstracts/Presentations

Lollis, C., Kondwani, K., & Robinson, L. Does meditation, anger management and lifestyle modification reduce blood pressure in African-American hypertensives? Paper presented at 15th Annual International Conference of the International Society for Hypertension in Blacks, Puerto Rico, July, 2000.

Kondwani, K. & Lollis, C.M. Self-healing Through Meditation: Theory, Research and Practical Applications. Paper presented at the 32nd Annual International Convention of the Association of Black Psychologists held in Ghana, July, 2000.

Kondwani, K. Transcendental Meditation: Its Effects on the Prevention and Treatment of Stress, Hypertension and Cardiovascular Disease. Paper presented at the American Association of Cardiovascular and Pulmonary Rehabilitation Annual Meeting, September, 2000.

Publications

There are currently no publications generated from this data. Reprints of any publications will be forthcoming.

Personnel

Faculty/Staff:

Charlie M. Lollis, Ph.D.:	Principal Investigator
Kofi Kondwani, Ph.D.:	Co-investigator
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TECHNICAL REPORT/ APPENDICES

This report details the recruitment, protocol administration, training and quality assurance procedures for this clinical trial.

Recruitment

Potential participants for the HEAD-SMART Program were identified from various community agencies throughout the Metro-Atlanta area. After identification, potential subjects received a phone call from the HEAD-SMART call team. This team consisted of 4 part-time staff members who worked during the evenings and on weekends. All potential participants gave prior permission to be contacted via the telephone to learn more about the research program. A standardized script was created for telephone recruitment (see Appendix A). Various sources were used to generate the current sample population.

Health Screenings

Health fairs were the major avenues of recruitment for this protocol. HEAD-SMART personnel and volunteers participated in community health fairs to perform blood pressure screenings. The pool of volunteers consisted of nurses, nursing students, and other assistants. Screening teams usually consisted of 3-4 staff/volunteers and lasted for approximately 4 hours. For longer screenings that lasted all day (8 hours) two screening teams were used in 4-hour shifts. Research personnel made contact with agencies including churches, local businesses, and other organizations. Community agencies contacted HEAD-SMART as well. As HEAD-SMART personnel took blood pressures, participants completed a prescreening form (see Appendix B) and were informed about the research project. If interested and eligible, they gave consent to be contacted by Head Smart Personnel to set up their first baseline appointment. Approximately 3476 individual were screened during this process. Out of the total number screened, 915 (26.3%) were eligible to participate in the study.

Physician Referral

Doctors located at Morehouse Medical Associates, Morehouse Family Practice Center, and local offices within the community were approached and informed about the MMRF research project. They were given Summary information regarding the project (see Appendix C). If these physicians had patients meeting the eligibility criteria for this study, they were requested to compete the "Physician's Referral Form" and return it to the HEAD-SMART Program (See Appendix D).

Referral by friend/relative

Word of mouth referral was an additional recruitment strategy for the project. Morehouse employees, participants in the research study, as well as other community members could refer individuals to the HEAD-SMART program. Potential participants were requested to call and schedule an initial appointment. These individuals were then prescreened for eligibility to enter the study.

Mail Recruitment

Letters were mailed from physicians at Morehouse Medical Associates and the Morehouse Family Practice Center to their clinical patients who were eligible to participate in the study. These patients also received a phone call briefly explaining the study and inviting them to set up a baseline appointment to confirm eligibility.

Media

Public service announcements and advertisements (see Appendix E) were prepared for recruitment through various media sources. Some of the avenues used included radio announcements, newspaper articles and advertisements, and the internet (Morehouse School of Medicine Website and emails). Potential participants were requested to call a general number to set up an initial appointment.

Outcome of Recruitment Strategies

Although the exact number of individuals screened for the entire study is unknown, it is estimated that approximately 15% of potential participants were not eligible, 31% of potential participants were not interested, and 13% of potential participants were unable to be contacted. Out of the total number of people recruited for this study, 124 scheduled a baseline appointment. Of those completing baseline, a total of 108 participants were randomized into one of the two treatment conditions. The additional 16 participants dropped out of the study at this point. There were 9 cohorts in each intervention. The health education condition contained a total of 55 women; 34 completed the intervention. The transcendental meditation condition contained a total of 53 women; 40 completed the intervention. A total of 74 participants entered the follow-up phase of the study; 68 completed. 3-month follow-up data was obtained on 39 participants.

Protocol Administration

Baseline Visits

The complete Research Protocol is located in Appendix F-I, including the consent form, HEAD-SMART summary sheet, protocol and intervention forms. Participants attended three baseline visits. Baseline visits were initially scheduled 2-7 days apart. The content of each visits were as follows:

Visit 1:
The participant was greeted by research personnel and asked to complete a preliminary screening form. If eligible according to this form, she then received a thorough explanation of the research program and the consent form, and was encouraged to ask questions. If willing, the participant gave consent to be included in the study and signed the consent form. The participant received a study summary sheet and a copy of her consent form to take home. Her blood pressure was then taken three times in the right arm, waiting approximately 5 minutes between each reading. If eligible according to her blood pressure, she was then scheduled for her second baseline visit.

Visit 2:
The participant participant's blood pressure was taken three times using the same standard set of guidelines as in the first visit. The patient was then asked to complete the medical interview, which was explained to her by research personnel. Upon completing the medical interview, lab procedures and fasting requirements were explained for the upcoming visit.

Visit 3:
The patient had blood and urine samples at the Morehouse Medical Associates laboratory. She then completed the reactivity lab, which consisted of mental and physical laboratory stressors. At the end of this visit, the participant was asked to wear an ambulatory blood pressure monitor. She was informed that the monitor would periodically take a blood pressure reading periodically throughout a 24-hour period. The participant was given a diary in which to record information regarding mood at each BP reading. Sleeping and waking time was also recorded. She was given detailed instructions on how to operate the monitor and record information in the diary. Participants were requested to choose a day in which wearing the monitor would not be too disruptive. If she was unable to wear the monitor on the day of their 3rd baseline visit, and additional appointment was made.

Eligibility to participate in the intervention was determined after the baseline visits. The preliminary screening form was reviewed during the first baseline visit to determine number of risk factors. An overall average blood pressure was calculated from the readings taken at all three baseline appointments. Once eligibility was verified, the participant entered the randomization process.

Randomization

Subjects were randomly assigned to one of two treatment conditions: transcendental meditation or a health education intervention. A random numbers table was generated so that selection into each intervention was equal. Subjects received a letter indicating the intervention group to which they were randomized, their instructor, and meeting time.

Intervention

The Intervention sessions took place at Morehouse Medical Associates. Upon arrival to the session, the participant was introduced to their instructor asked to complete an intervention expectancy form. Both interventions consisted of 13 sessions lasting approximately 1-½ hours in length. Attendance was taken at each session. Participants were asked to keep a diary of their morning and evening practices in the transcendental meditation group. They were asked to keep a diary recording their practice of a lifestyle modification in the health education group. Participants received a certificate of completion at the end of the 13-week intervention. They were also scheduled for their follow-up appointment at that time.

Outline of TM instruction and follow-up intervention program

The core instruction in the Transcendental Meditation technique involved a seven-step course over five days, which followed the standard format offered in the U.S. by Maharishi Vedic Universities and Maharishi Vedic Schools (Roth, 1994). Most sessions lasted 1-1.5 hours with the exception of the personal interview (about 10 minutes). The general format of most sessions included group meditation plus a lecture/discussion or videotape.

Visit 1. Introductory/preparatory Lecture (Step 1& 2) —a review of previous scientific research, the mechanics and origin of the TM program and a vision of possible benefits through regular practice.
Visit 1. Personal Interview (Step 3) —interview with a qualified teacher of the TM program.
Visit 2. Personal Instruction (Step 4) —private individual learning of the TM technique.
Visit 3. First Day of Checking (Step 5) —verifying the correctness of practice and further instruction.
Visit 4. Second Day of Checking (Step 6) —understanding the mechanics of the TM technique from personal experiences.
Visit 5. Third Day of Checking (Step 7) —understanding the mechanics of the development of higher states of wellness and health.

Follow-up Program: (**Visit 6-13**) Following the above intensive phase of the intervention, the TM instructor conducted weekly follow-up sessions for the first month (4 sessions) consisting of a 20 minute group meditation and a short inspirational video tape of people who practice the TM technique and how it effects their daily lives. In month two and three, cohorts met biweekly (4 sessions). The total number of meetings was 13 for each cohort. Each 1.5-hour session consisted of a twenty-minute group meditation and included checking of correct practice of the TM technique, advanced seminars to ensure complete understanding of benefits of the practice and its physiological, psychological and behavioral health benefits. The videotapes used in the sessions were:

1) "Maharishi Speaks on the correct Practice of the TM technique"

2) "Accelerating the growth of Enlightenment"
3) "Life according to Natural Law"
4) "Strengthening the Individual, Family and Community"
5) "TV News reports on TM Research"
6) "Rehabilitation and TM in Senegal"

The final meeting consisted of a graduation-potluck celebration where the TM Instructor and the Principal Investigator issued "Certification of Completion" certificates to participants signed and dated.

Outline of Health Education Intervention Program

The Health Education intervention was designed to be a control comparison for the TM intervention. The total number of session was equal to that of the TM group so that both conditions were matched for time and attention. A 15 Module intervention was conducted in the 13 sessions (see Appendix J).

Follow-up

Participants completed post-intervention blood pressure and laboratory assessments similar to the baseline visits. During their 12^{th} and 13^{th} intervention sessions, three blood pressure readings were taken for each participant. After completing the intervention the client was scheduled for a follow-up appointment in which she completed three additional blood pressure readings, a medical interview, and the reactivity lab. Participants were informed that they would be contacted and invited to return three months later for another assessment of blood pressure.

3-Month Follow-up

Participants were scheduled to be seen three months after their initial follow-up appointments. At this time participants received blood pressure assessment, medical interview, reactivity laboratory, and 24-hr ambulatory blood pressure monitoring.

Training/Quality Assurance

Training

The HEAD-SMART Program employed several staff members to run a day and evening clinic. The clinic was also open on Saturday. The HEAD-SMART Clinic hours of operation was from 8:30AM to 9:00 PM Monday-Friday, and from 9:00 AM – 5:00 PM on Saturday. A team of approximately 3 research assistants and part-time laboratory coordinator was available during the evenings and weekends. Regular full-time staff were responsible for the operation of the day clinic. Research staff responsible for implementation of the research study received intensive training and monitoring to insure proper and standard delivery of the research protocol. Staff was selected based on their previous experience in conducting research protocols. Full-time staff included the Project Coordinator, Program Assistant, Laboratory Coordinator, Data Manager, Health Educator, TM Instructor, and a research assistant. Several part-time research assistants were hired for the evening clinic and the calling/recruitment team. Training methods included instruction and handouts from the project coordinator, direct observation of research procedures, and implementation of research procedures under observation by the project coordinator or other trained staff. All staff received training in assessing blood pressure and served as back up for baseline labs. Training in the assessment of blood pressure was performed in accordance with the guidelines outlined in the Joint National Committee Report on the Detection, Evaluation and Treatment of Blood Pressure (JNC-6).

Project Coordinator

The project coordinator was trained by the principal investigator to manage all activities related to overseeing the implementation of the recruitment, screening, baseline, and follow-up assessments. The project coordinator supervised day-to-day management activities, developed project forms and served as the project liaison to community agencies. She also coordinated the training activities of other staff members. The project director received approximately 160 hours of training (one month).

Program Assistant

The program assistant assisted in the management of daily program activities including recruitment, scheduling, maintaining contact with participants, management of budgets, supplies, and other administrative duties. The program assistant received approximately 40 hours of intensive training.

Laboratory Coordinator

The laboratory Coordinator manages all aspects of the cardiovascular reactivity lab. Duties included management of blood chemistry and reactivity/ambulatory data, preparation and participation in blood pressure screenings, coordination of project equipment inventory, assisting the project coordinator in the updating of the master code list. The laboratory coordinator received 160 hours of intensive training.

Data Manager
The Data Manager responsible for coordinating the data entry and data management process. Duties included setting up the project data bases, creating the data dictionary, coordinating data entry, conducting necessary power analyses and statistical analyses, and assisting in preparation of reports/manuscripts. The data manager received approximately 80 hours of training.

Health Educator
The Health Educator was responsible for the instruction of the Cardiovascular Health Education intervention. This included assisting in the development of the intervention curriculum, initiating and maintaining contact with class participants, assisting in data collection of intervention data. The Health educator received 40 hours of intensive training.

TM Instructor
The TM instructor received his instruction from the TM Organization. The TM technique has been taught worldwide since 1957. Approximately two million people in the US and six million people worldwide have participated in the standard TM course over the last 40 years.

Research Assistants
Research assistants were hired to assist in implementation of the research protocol. Their duties included assisting in blood pressure screening and assessments, implementation of baseline visits, telephone calling to schedule appointments, data entry, and other implementation tasks. Each research assistant received 40 hours of intensive training.

Quality Assurance

Quality assurance procedures were implemented to insure standardization of implementation throughout the protocol. A data progression hierarchy was developed to insure that all information obtained from participants was checked thoroughly by more than one research staff member. Research staff was responsible for maintaining the integrity of specific areas of the research protocol.

Baseline/Follow-up Data
A standard procedure for each aspect of the research protocol was developed for the purpose of quality assurance. Quality assurance measures for recruitment, baseline and follow-up visits were conducted by the project coordinator and the cardiovascular lab coordinator. Upon completion of the standardized baseline questionnaires, the lab coordinator was responsible for reviewing the baseline protocol; calculating all blood pressure averages, reviewing the questionnaires for accuracy and completion and obtaining any missing information. The project coordinator or PI reviewed these protocols again before preparing them to be processed by data entry. In addition, the PI randomly audited files to ensure accuracy of data. Once entered into the computer, files were randomly audited to ensure accuracy in the transfer of hard data to electronic files. All data was saved on our hard drive and backed up on disk daily. The quality control procedures for data are outlined in Appendix K.

Intervention Data

The TM instructor and the Health Educator collected intervention Data. All intervention data was reviewed on a weekly basis by the project coordinator. The instructors handled any missing information and/or discrepancies.

Blood Draw Quality Control

Additional tubes of blood were collected and analyzed for quality control purposes. A total of 10% of the blood samples were re-analyzed. A detailed description of this process is included in Appendix L.

Ambulatory Data

The cardiovascular laboratory coordinator maintained ambulatory Data. A log of the specific machine worn by each participant was kept. Batteries were used only once to insure that each machine would maintain power for the entire 24-hour period. Participants' data was downloaded from the machine to a computer file immediately following return of the ambulatory unit.

Medical Back-Up Procedures

Medical back-up procedures were established to handle certain medical adverse events. Dr. George Rust served as the primary medical physician to handle emergencies for the study. In addition, other medical doctors/residents, employed by Morehouse Medical School were to be contacted in the event of such emergencies. Details regarding the specific events and medical back-up procedures can be found in Appendix M.

Assurance of Confidentiality

To insure confidentiality, two files were created for each participant. A file with the participants name contained all non-data information with identifying markers such as name, address, and social security numbers. This included contact and compensation information. A file listed by subject number was created and contained all pertinent data for the study. All identifying information was removed from this file. A master list of participants and their subject numbers was kept in a separate secure file and maintained by the project coordinator.

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APPENDICES

Appendix A:	Telephone Recruitment Script
Appendix B:	Preliminary Screening Form
Appendix C:	Project Description
Appendix D:	Physician Referral Form
Appendix E:	Public Service Announcements/Advertisement
Appendix F:	Human Subjects Informed Consent Form
Appendix G:	Project Summary Form
Appendix H:	Preliminary Screening Form Blood Pressure Records Cardiovascular Reactivity Lab Forms Psychosocial Questionnaires
Appendix I:	Intervention Forms
Appendix J:	Health Education Manual
Appendix K:	Data Management Quality Control Procedure
Appendix L:	Laboratory Quality Control Procedure
Appendix M:	Medical Backup Procedure

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APPENDIX A

HEAD-SMART SCRIPT FOR 1st VISITS

(12/1/98 ch)

Hello, may I speak with _____. Hello, my name is _____ and I am calling with the Morehouse School of Medicine HEAD-SMART program. We took your blood pressure on _(date)_____ at ____(location)_____. The reason for my call is that at the time we took your blood pressure it was higher than what is recommended and as you may know this increases your risk for developing heart disease. Now, here at Morehouse, we have programs for which you may qualify that teach you how to lower your blood pressure without the use of medications. If you are taking medication, we do not ask that you alter them in anyway. **All of our services are free and if you complete the program we offer you a minimum of $150.00 dollars as reimbursement for your travel to our clinic.**

Mr./Mrs. _____ I'd like to schedule an appointment with you to visit our **FREE** Blood Pressure clinic. Your first visit will only take about 30 minutes. While you are here one of our trained staff members will speak with you about ways to lower your blood pressure and introduce you to our programs. Please note that we can provide you with a written doctor's excuse for missed time at work or school if necessary.

Currently, our clinic is open M – F. On M, W, F we are open from 9-5 and we accept our last appointment at 3:00. On T and Th we have extended hours. We are opened from 9-9 and we accept our last appointment at 6:30. If these times are not convenient for you we will work to accommodate your schedule. Which date and time is best for you? *(At this point if an individual appears to be having a difficult time making an appointment we can assist them. Please feel free to make suggestions for the earliest available time. For example, you may start by asking them which day of the week is best for them. Afterwards ask them about a convenient time. With this information you can then suggest an appointment. For example, "Does Wednesday at noon seem like a good appointment time for you?).*

Thank you Mr./Mrs. _____, I have received your appointment information. Now I would like to take a few minutes to give your some important information about your clinic visit. We are located at 75 Piedmont Ave., 8th floor in the Citizen's Trust Bank building. Once you get off the elevator there will be signs directing you to **HEAD-SMART**. As for parking, make sure you park in the parking deck entrance on JW Dobbs for daytime appointments. All visitors must park on the 1st or 2nd level down. *(If coming in after 5- Instruct them to park in the upper lot facing the MMA Piedmont entrance).*

Please do not consume any caffeine or nicotine at least one hour before your visit b/c this will increase your blood pressure. Also, if you are taking or have recently taken any over the counter/or prescribed cold/cough or sinus medications please inform one of our staff members. Many of these medications have also been known to elevate Blood Pressure.

As a reminder, we look forward to seeing you on _(date_)_____ at ___(time)_____. You will receive a reminder call 1-3 days before your scheduled appointment. Please contact us at (404) 756-1415 if you have any questions.

Thank you Mr./Mrs. _____ and have a good day/evening.

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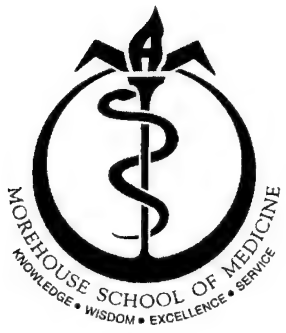
APPENDIX B



MOREHOUSE SCHOOL OF MEDICINE
Dept. of Family Medicine – Behavioral Medicine Research Center
PRELIMINARY SCREENING FOR HEAD-SMART

MMRF ☐
S&A ☐

DATE: _____

GENDER: FEMALE _____ MALE _____ AGE: _____ RACE: _____

HEIGHT: _____ WEIGHT: _____

NAME: _____

ADDRESS: _____

_____

PHONE NUMBER (S): (HOME) _____ (WORK) _____

Have you been diagnosed with hypertension? Yes ☐ No ☐

Are you currently on medication for high blood pressure? Yes ☐ No ☐
Please list the medications: _____

Do you inject insulin, have kidney disease, or are pregnant/breast feeding? Yes ☐ No ☐

STAFF USE ONLY
CURRENT BLOOD PRESSURE READING (S) – *RIGHT ARM.* BP1 _____ BP2 _____

COMMENTS _____

SCREENING SITE: _____ STAFF INITIALS: _____

MOREHOUSE SCHOOL OF MEDICINE
Dept. of Family Medicine – Behavioral Medicine Research Center
PRELIMINARY SCREENING FOR HEAD-SMART

MMRF ☐
S&A ☐

DATE: _____

GENDER: FEMALE _____ MALE _____ AGE: _____ RACE: _____

HEIGHT: _____ WEIGHT: _____

NAME: _____

ADDRESS: _____

_____

PHONE NUMBER (S): (HOME) _____ (WORK) _____

Have you been diagnosed with hypertension? Yes ☐ No ☐

Are you currently on medication for high blood pressure? Yes ☐ No ☐
Please list the medications: _____

Do you inject insulin, have kidney disease, or are pregnant/breast feeding? Yes ☐ No ☐

STAFF USE ONLY
CURRENT BLOOD PRESSURE READING (S) – *RIGHT ARM.* BP1 _____ BP2 _____

COMMENTS _____

SCREENING SITE: _____ STAFF INITIALS: _____

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APPENDIX C

Hypertension and Risk Factors for Cardiovascular Disease:
An African-American Health Challenge

The Problem:

- One out of four African-Americans have high blood pressure.
- African-Americans are three times more likely to have high blood pressure than Whites.
- Being overweight, high sodium intake, high cholesterol, smoking, drinking alcohol, sedentary lifestyle and stress correlate with high blood pressure.
- High blood pressure is a silent killer! It has no symptoms and if left untreated can lead to heart attack, stroke, kidney failure, blindness and death.
- Hypertension is the number one preventable cause of over 65,000 excess deaths annually among African-Americans.
- The Joint National Committee on the prevention, detection, evaluation and treatment of hypertension **strongly** recommend lifestyle modification/stress reduction therapies as a primary or adjunctive treatment for hypertension.

The Solution:

The Behavioral Medicine Research Center's
H.E.A.D.-S.M.A.R.T. Programs
(Health Education and Diet—Stress Management/Anger Reduction Therapies)

Our Research Programs Provide **FREE**:

- Blood pressure checks
- 24-hour blood pressure assessment
- Laboratory tests required by the study
- Test results sent to your doctor
- Training in transcendental meditation, anger management or health education
- Intensive Follow-Up

So, Don't Delay! Get a Head-Start Against Heart Disease with
H.E.A.D.-S.M.A.R.T.

Morehouse School of Medicine
Department of Family Medicine
Behavioral Medicine Research Center

H.E.A.D.-S.M.A.R.T. Programs
(**H**ealth **E**ducation **A**nd **D**iet-
Stress **M**anagement/**A**nger **R**eduction **T**herapies)

Managing Multiple Risk Factors for Cardiovascular Disease

is a 13-week intervention for African-American women 18-70 years old with blood pressures of 130/85 to 159/104 and at least 2 additional risk factors for cardiovascular disease. The program is designed to modify cardiovascular risk factors with 1) health education/lifestyle modification or 2) transcendental meditation. Eligible participants are randomly assigned to receive one of these two treatments. Prior to being enrolled in a therapy program, all participants must come to the clinic for 3 initial assessments to determine eligibility and for laboratory testing. At the second visit, they will complete a medical interview and questionnaires (1.5-2 hours) about their health behaviors, perceived stress, coping behaviors, etc. At the third visit, they will complete a blood draw to measure lipids, catecholamines and insulin levels. They will also complete a laboratory stress assessment (1-1 ½ hours) where blood pressure, heart rate and blood flow are measured in response to doing different tasks. Following this assessment, participants will be fitted with a device which will take their blood pressure over a 24-hour period as they conduct their normal daily activities. Within one month of this initial assessment phase, participants will be randomly assigned to attend treatment groups. The Health Education group will meet for 13 weekly visits while the Transcendental Meditation group will meet 5 consecutive days, then every other week for 4 months. All groups will last 1½ hours during the intervention period. Following the intervention, participants will complete a follow-up assessment consisting of an interview/questionnaires and another blood draw, laboratory session and 24-hour blood pressure assessment. At this time participants are enrolled in a follow-up phase where they are contacted to come back in 3 months to repeat the interview/questionnaires, blood draw, laboratory assessment and 24-hour blood pressure monitoring. **A stipend of $160.00 to reimburse you for travel expenses to and from the clinic is provided at the completion of the study.**

If participants are eligible for **both H.E.A.D.-S.M.A.R.T. programs, participants must agree to be randomly assigned to one of the programs.*

Get a Head Start Against Heart Disease with . . .

H.E.A.D.-S.M.A.R.T!
(Health Education and Diet-Stress Management/Anger Reduction Therapies)

If your blood pressure is 130/85 mmHg or more you may be at increased risk for developing hypertension or heart disease.

Learn how to effectively manage your blood pressure and reduce your risk for heart disease with our non-drug therapies.

Contact Dr. Charlie M. Lollis at the Behavioral Medicine Research Center to learn more about our H.E.A.D.-S.M.A.R.T. programs and to determine your eligibility.

Morehouse School of Medicine
Behavioral Medicine Research Center
75 Piedmont Ave., Suite 800
Atlanta, GA 30303
(404) 756-5250

Morehouse School of Medicine

DATE: _____

Blood Pressure Reading(s):

_____

_____

_____

Thank you for your participation!

Question?

Q: Are You Stressed?

Do You Have High Normal or High Blood Pressure (130/85 mmHg or higher)?

We Have The Answer!

A: Get a Head-Start with **"H.E.A.D.-S.M.A.R.T"**

Morehouse School of Medicine
Department of Family Medicine
Behavioral Medicine Research Center's

Health	**S**tress
Education	**M**anagement
And	**A**nger
Diet	**R**eduction
	Therapies

Reduce stress, lower blood pressure, prevent heart disease and *improve the quality of your life* with our **non-drug** therapies for African-Americans: Lifestyle Modification, Transcendental Meditation, Anger Management/ Relaxation Techniques

Did You Know . . .?

- One out of four African-Americans have high blood pressure
- African-Americans are three times more likely to have high blood pressure than Whites
- Being overweight, eating too much salt, high cholesterol, smoking, drinking alcohol, not getting enough exercise and stress are associated with high blood pressure
- High blood pressure is a silent killer! It has no symptoms and if left untreated can lead to heart attack, stroke, kidney failure, blindness and death
- Hypertension is the number one preventable cause of over 65,000 excess deaths annually among African-Americans
- **Early detection and treatment are extremely important**
- You can control your blood pressure and get a head start against heart disease with H.E.A.D.-S.M.A.R.T.

What is H.E.A.D.-S.M.A.R.T?

H.E.A.D-S.M.A.R.T. consists of two programs designed to find alternative ways to treat hypertension and reduce risk for heart disease in African-Americans. These studies are sponsored by the National Institutes of Health and the Department of Defense.

Why Should You Take Part in H.E.A.D.-S.M.A.R.T.?

If you qualify to join our program you may receive **free**

- Blood pressure checks
- 24-hour blood pressure assessment
- Laboratory tests required by the study/ Follow-up assessments
- Test results sent to your doctor at your request
- Training in transcendental meditation, anger management or health education

How do you find out if you are eligible?

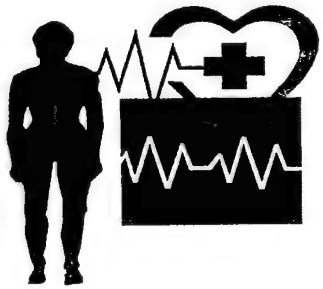
If you are an African-American, between 18 and 70 years of age and your blood pressure is at least 130/85 mmHg you may be eligible for one of our H.E.A.D.-S.M.A.R.T. programs. Call us today and we will arrange a free clinic visit to tell you more about our programs and find out if you might qualify for participation.

Check Your Risk

Place a check next to the item if it is applicable to you.

- ☐ Do you have a relative (mother, father, brother or sister) who has/had high blood pressure?
- ☐ Is your blood pressure 130/85 mmHg or higher?
- ☐ Are you more than 10% over the ideal body weight for someone of your height?
- ☐ Do you have a tendency to eat salty foods or use extra salt on your food?
- ☐ Do you have high cholesterol?
- ☐ On average, do you drink more than 2- 3 alcoholic drinks per day?
- ☐ Do you smoke cigarettes?
- ☐ Do you avoid exercising regularly?
- ☐ Do you experience significant amounts of stress?

If you checked any of the above, you may be at increased risk for developing hypertension or heart disease. So, don't delay—get a head start against heart disease with HEAD-SMART!



Morehouse School of Medicine
Department of Family Medicine

MANAGING MULTIPLE RISK FACTORS FOR CARDIOVASCULAR DISEASE

DAMD17-95-C-5067

APPENDIX D

How do I make a referral to the Behavioral Medicine Research Center's (BMRC) H.E.A.D.-S.M.A.R.T. Programs?

It is as easy as 1, 2, 3!

1. Determine if your patient has blood pressure ≥ 130/85 mmHg.

2. Complete a physicians referral form with your patient and return it to the designated area in the FPC.

3. **We do the rest!** Patient will be scheduled for a clinic visit within 2 weeks of referral to determine eligibility for the program.

Dr. Charlie M. Lollis, Director
Behavioral Medicine Research Center
75 Piedmont Ave., Suite 800
Atlanta, GA 30303
(404) 756-1415

(This form may be duplicated)

PHYSICIAN'S REFERRAL FORM

Department of Family Medicine
Behavioral Medicine Research Center

H.E.A.D.-S.M.A.R.T.
(Health Education And Diet/Stress Management Anger Reduction Therapies)

Part A: To be completed by referring physician

I recommend the undersigned patient who is currently under my medical care for the MSM H.E.A.D.-S.M.A.R.T. programs as an adjunct to treatment. I understand that patient must meet eligibility requirements to enroll in the program and that any medical information significant to this patient's treatment will be available to me only with the patient's expressed written consent. Likewise, I will communicate pertinent medical history information to the Behavioral Medicine Research Center only upon obtaining a signed release of information.

_____ _____
Physician's Signature Date

Patient's Blood Pressure:

Date Blood Pressure Assessed: _____

Part B: To be completed by patient

Patient Name: _____

Daytime Phone Number: _____
Evening Phone Number: _____

Patient Address: _____

Contact Dr. Charlie Lollis at the Behavioral Medicine Research Center, 75 Piedmont Ave., Suite 800, Atlanta, Georgia 30303; (404) 756-1415 for an appointment.

Morehouse School of Medicine
Department of Family Medicine

MANAGING MULTIPLE RISK FACTORS FOR CARDIOVASCULAR DISEASE

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APPENDIX E

MOREHOUSE SCHOOL OF MEDICINE

Department of Family Medicine
Behavioral Medicine Research Center

Contact: Celedor Hutto, Research Coordinator, phone (404) 756-1415

Public Service Announcement

The Morehouse School of Medicine is currently seeking African-American women, both civilian and military, to participate in a program to reduce risk for heart disease without the use of medications. Participants will receive instruction in Health Education, Transcendental Meditation, or Anger/Stress Control. Transcendental Meditation, which is a form of relaxation and our Stress/Anger Control classes, will teach participants relaxation techniques that have been effective avenues for lowering blood pressure, stress and reducing anger. All instructions, materials and evaluations are FREE. If your blood pressure is 130/85 or higher and you would like to learn more about our programs, contact us at (404) 756-5250. Once again the number is (404) 756-5250.

Contact: Ms. Teresa Stewart, program assistant, phone (404) 756-1415

Church Announcement

The Morehouse School of Medicine is offering free health education and relaxation programs to treat high blood pressure and reduce risk for heart disease in African-Americans without altering or changing your medication. Participants will receive instruction in health education, meditation or anger/stress management. All services are free and participants who complete the program will be compensated $150 for travel and expenses associated with coming to the clinic. If you are between 18-70 years of age and have high blood pressure and would like to learn more about our programs, contact us at 404-756-5250.

Contact: Ms. Teresa Stewart, Program Assistant, phone (404) 756-1415

Public Service Announcement/Radio Advertisement

The Morehouse School of Medicine is conducting research studies in treating high blood pressure in African Americans. These programs will examine the effectiveness of relaxation therapies for managing high blood pressure and reducing risk for heart disease without altering or changing your medications. Participants will receive instruction in one of the following areas: health education, meditation or anger/stress management, all of which have shown effectiveness in reducing blood pressure. All services are free and participants who complete the program will be compensated $150 for travel and expenses associated with coming to the clinic. If you are between 18-70 years of age and you have high blood pressure and would like to learn more about our programs, contact us at 404-756-5250. Once again, the phone number is 404-756-5250.

350 African-Americans needed to participate in programs to reduce High Blood Pressure

The Morehouse School of Medicine needs African-American participants for their H.E.A.D.-S.M.A.R.T. (**H**ealth **E**ducation **A**nd **D**iet – **S**tress **M**anagement **A**nger **R**eduction **T**herapies) programs.
The focus of these programs will be to find ways to lower High Blood Pressure, stress, and reduce risk for heart disease without the use of drugs.

One out of four African-Americans have high blood pressure and Blacks are three times more likely to have this disorder than whites. High blood pressure has no symptoms and if left untreated can lead to heart attack, stroke, blindness, kidney failure, and death. High Blood pressure is preventable, therefore individuals are encouraged to have their blood pressure checked regularly and receive treatment early.

H.E.A.D.-S.M.A.R.T. can be an important part of your decision to detect and treat high blood pressure. Our programs are funded by the National Institutes of Health and the Department of Defense. Participants in our programs will have their blood pressure, responsiveness to stress, and risk for heart disease examined. Also, participants will be involved in one of the following types of classes: health education, relaxation and stress/anger control.

Our health education classes will provide personal guidance for making healthier decisions for weight reduction, food selection, and stopping negative health habits. The relaxation and stress/anger control classes will teach participants relaxation techniques, which have been effective avenues for lowering stress, blood pressure, and reducing anger. A study published by the journal *Hypertension* showed that a certain form of relaxation -Transcendental Meditation – was as effective as pressure- reducing medications in lowering the blood pressure in blacks between the ages of 55 to 85. Often individuals taking pressure-reducing medications complain about negative side effects like dizziness, headaches and decreased sexual arousal. Our programs can effectively lower blood pressure without the unwanted side effects associated with some medications.

If you are an African-American between 18 and 70 years of age and your blood pressure is at least 130/85 mmHg you may qualify for one of our H.E.A.D.-S.M.A.R.T. programs. Call us at (404) 756-5250 for a free clinic visit and to determine your qualification. We encourage you to be HEAD-SMART and let us work together to get a head start against high blood pressure and heart disease.

Morehouse School of Medicine
Department of Family Medicine

MANAGING MULTIPLE RISK FACTORS FOR CARDIOVASCULAR DISEASE

DAMD17-95-C-5067

APPENDIX F

CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

Title of the Research Study: Managing Multiple Risk Factors for Cardiovascular Disease

Sponsor(s) of the Research Study: Department of Defense

Principal Investigator(s) of the Research Study: Charlie M. Lollis, Ph.D., Assistant Professor, Department of Family Medicine, Morehouse School of Medicine

Invitation to Participate:
You are invited to participate in this research study. The following information is provided so that you may decide whether or not you wish to participate. Eligibility requirements to participate in this research will be described to you. Approximately 200 African-American volunteers (100 civilian women and 100 military women) from the Atlanta Metropolitan area with uncontrolled mild hypertension (i.e. blood pressure 130-160/80-104 mmHg) and two additional self-reported risk factors for heart/circulatory disease are anticipated to participate in this study.

Information on the Research Project:
The purpose of this study is to compare a stress reduction therapy for managing hypertension with a health education control group. All of the testing, intervention and educational procedures will be conducted at the Behavioral Medicine Research Program located at 75 Piedmont Avenue, Atlanta, GA 30303. Some intervention groups may be conducted at 505 Fariburn Rd., Atlanta, GA 30331.

The whole project will last 9 months. There are three phases to this project.

Phase I

You will be required to visit the clinic a total of 3 times for:

1) routine blood pressure checks;
2) a stress test (that will last about 1 hour and 30 minutes); this consists of having your blood pressure/blood flow measured while engaging in different tasks such as mental arithmetic, hand grip, interview, etc.
3) a 24-hour blood pressure monitoring session;
4) a blood draw to examine cholesterol and other biological risk factors; and
5) to complete an interview and questionnaires about your lifestyle. This last task will take about 45 minutes to an hour to complete.

Phase II

You will be randomly assigned (by chance like the flip of a coin) to receive one of two different treatments for stress reduction, anger management/meditation therapy or health education. You will be required to make 4 daily visits, followed by once a week sessions for 10 weeks.

Phase III

The follow-up phase is last. This involves a second stress test the same as described in phase I and an interview or questionnaires about your lifestyle. This will occur within 1 month following your last group session and again 6 months later. During the period between your last group session and your follow-up visit you may be asked to come in once a month for us to check on your individual progress.

A brief description of the intervention groups follows.

I. Meditation: The Anger Management/meditation therapy will consist of weekly sessions that focus on how to cope with stressful situations without becoming overly angry. You will also be taught a simple meditation procedure, practiced twice a day for 20 minutes (once in the morning and once in the evening) while sitting with the eyes closed. During meditation the body becomes relaxed and the individual becomes more organized in their thinking.

II. Preventive Cardiology Counseling: The participants in this group will receive counseling about diet, salt, smoking, weight, exercise and the effects of these factors on controlling cardiovascular risk factors. You will not be treated with medications.

Explanation of Procedures:
You will have your blood pressure, heart rate and forearm blood flow measured in response to several tasks in order to develop a profile of your blood pressure in different situations (e.g. hand grip, math challenge, etc.). This is with automated blood pressure equipment. Following the stress testing, you will be fitted with a 24-hour automatic blood pressure monitoring device that will measure and record your blood pressure every 30 minutes over a 24-hour period. You will also have a blood draw done to develop a profile of other risk factors for heart and circulatory disease (e.g. cholesterol, fatty acid levels, etc.).

Potential Risks and Discomforts: It is possible that the laboratory stress tests (cold pressor, math challenge, hand grip, structured interview) may cause rapid but non-permanent increases in blood pressure. Blood pressure will be monitored frequently during these procedures and stress testing will be terminated if blood pressure during any task increases above 180/110 mmHg. If blood pressure remains elevated, you may be at risk for stroke, coronary heart disease or heart attack. You can remain in the study if your diastolic blood pressure remains in the range of 90 to 104 mmHg, but if you are not under a physician's care will be referred for anti-hypertensive drug therapy. You may feel minor pain in the area where the needle is used to draw blood from you vein. There is a chance of bruising and a small chance of infection associated with blood withdrawal. Some people feel faint when blood is withdrawn. Please inform the medical personnel if this has happened to you in the past.

It is possible that you may become emotionally distressed during the stress test or interventions. If you become overly distressed you will be able to speak with Dr. Charlie Lollis or Dr. Edith Fresh who are clinical psychologists or to the therapy leaders. If necessary you will be referred for additional treatment. Physicians from the department of family medicine will assist in any medical emergencies. To minimize risks, **you are to report any side effects even if you consider them mild and not bothersome to the principal investigator, Dr. Charlie M. Lollis.**

Usual Treatment: The usual treatment for cardiovascular risk factors include drug therapies and lifestyle management through nutritional counseling/health education. Drug treatment is not available directly through the study. If you are currently not on drug therapies and would like this form of treatment, you will be referred to a community physician. This will not affect your ability to participate in the study.

Potential Benefits: You and your physician will be given information about your responses to to the therapy to which you were assigned. You will both receive information on whether clinic blood pressure and blood pressure outside the clinic is reduced by stress reduction therapies or health education, information as to whether or risk factors for heart and circulatory disease are reduced and information as to whether your quality of life is improved by these therapies. This information alone will help you make decisions about your medical treatment. You may be able to safely lower your medication dosages and still maintain normal blood pressure. You may learn how to take your blood pressure and other medications more regularly as a result of participating in this study. A last benefit is that you could develop a healthier and more peaceful daily life.

Alternatives to Participation: While there might be other ways to obtain the same procedures that are offered in this research study, they are offered to you in the study at no cost. To obtain the 24-hour ambulatory blood pressure assessment would be quite expensive, but it could be obtained through their physician. Certain information from the stress testing can be obtained only from being a participant in a research study or a special laboratory that performs these assessments.

Financial Obligations:
All procedures, visits and treatments used in this study will be provided to you free of charge.

Compensation for Participation: Participants will be provided with $10.00 per visit (14 visits) after throughout the intervention period to compensate for travel/parking expenses associated with participation in the interventions. They will receive $15.00 for their immediate follow up assessment and $15.00 compensation for their 6-month follow-up visit. Individuals are not

compensated during the 3-week pre-intervention baseline assessment. No compensation will be provided for missed intervention sessions or to individuals who decide to withdraw or who are dismissed from the study. Compensation for expenses incurred through the 10 weeks/immediate follow-up visit ($155.00) is paid upon completion of the immediate follow-up phase and the remaining $15.00 payable upon completion of the 6-month follow-up.

Assurance of Confidentiality: The identity of the research participant will be known only by the principal investigator and technical staff conducting the study. Any information obtained about participants which could identify them will be kept in strict confidence. However, representatives of the study sponsor (***Department of Defense)*** and/or the Morehouse School of Medicine's Institutional Review Board -- the committee that approved this research project -- may have access to research records. Participants will not be identified in any way in any publications, scientific or other journals, papers or in any reports made on this research at scientific meetings.

Emergency Care and Compensation for Injury: In the event you should experience an injury as a direct consequence of participation in this research study, reasonable, immediate medical care to treat such injury will be provided at no cost by Morehouse School of Medicine and/or other sponsors of the research study to the extent that such treatment costs are not reimbursable through your health insurance. At no time, however, will public assistance medical care benefits be billed for treatment of research-related injuries. Morehouse School of Medicine has not made provisions for compensation of physical care, hospitalization, loss of income, pain, suffering, or any other form of compensation beyond immediate treatment. This statement is not meant to imply that participation in this research constitutes a waiver of any legal rights or remedies available to you. If you believe you have suffered a research-related injury, you should immediately notify all contact persons listed in this form.

Persons to Contact: If you have any questions about the research project or in the event of a research related injury or emergency, contact **(Dr. Charlie M. Lollis at (404) 756-1415. Emergency calls only should be directed to (770) 707-6291 if cannot be reached by alternative number.)** If you have any questions regarding your rights as a participant in this research project you may contact Morehouse School of Medicine's Institutional Review Board at (404) 752-1711.

Voluntary Participation and Right to Withdraw from the Research Study:
Participation in this research is voluntary and you may decide not to participate or to withdraw at any time. Withdrawal from the study will not adversely affect your relationships with the investigators or with Morehouse School of Medicine. The decision to withdraw from this study will not jeopardize your medical care or result in any loss of benefits to which you may otherwise be entitled. If you begin the study and later decide to withdraw or if you are withdrawn from the study for any reason, you will be advised at that time of any possible alternatives available to you and given any information that may be important to your health.

Significant New Research Findings:
Any new information developed during the course of this research that may relate to your willingness to continue in the study will be provided in a timely manner.

PATIENT/VOLUNTEER CONSENT STATEMENT

I understand that participation in this research project is voluntary. I may withdraw from this study at any time, for any reason, or for no reason. If I decide to withdraw, I shall notify the doctor of this decision. I freely consent to take part in this clinical research study conducted under the supervision of Dr. Charlie M. Lollis. I understand that the study may involve some risk/discomforts to me which I have read about in this form and which have been carefully explained to me. My participation in this project has been clearly explained to me and I have had ample opportunity to ask questions about the study and to decide to participate. My questions have been answered to my satisfaction and I am free to ask further questions about the study at any time. I have been advised of the materials and procedures used in this study and I understand what I am to do in this research study.

I certify that I am at least 18 years of age (and, if female, I am neither pregnant nor breast feeding -- if applicable).

_____
Name of Patient/Volunteer Printed

_____ _____
Signature of Patient/Volunteer Date

_____ _____
Signature of Witness Date

My signature as witness certifies that the patient/volunteer signed this form by his/her own free will in my presence.

_____ _____
Signature of Principal Investigator Date

In my judgment the patient/volunteer, having been fully informed of the research project described herein, has the legal capacity and is knowingly and willingly giving informed consent to participate in this research project.

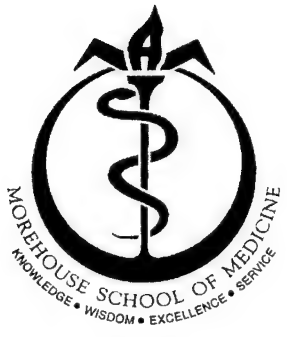
(rev. 2/28/96)

Morehouse School of Medicine
Department of Family Medicine

MANAGING MULTIPLE RISK FACTORS FOR CARDIOVASCULAR DISEASE

DAMD17-95-C-5067

APPENDIX G



H.E.A.D.-S.M.A.R.T.

(Health Education and Diet/ Stress Management Anger Reduction Therapies)

Did you know you could potentially change and save your life in a 24-hour day?

Our HEAD SMART Programs require a total time commitment of 24 hours for you to complete our assessment and intervention process.

HEAD SMART programs offer lifestyle educational programs to teach you how to manage your blood pressure and other risk factors for heart disease. Our meditation and stress and anger management programs provide training in relaxation therapies that help manage blood pressure. All programs have shown proven effectiveness in some patients with high blood pressure in prior research studies.

Phase 1: 3-week assessment period

- visit 1: 3 blood pressure readings
  program information
  (30 minutes)
- visit 2: 3 blood pressure readings
  medical history questionnaire
  (2 hours)
- visit 3: 3 blood pressure readings
  non-invasive stress test (reactivity lab)/blood draw
  (if applicable)
  (1-2 hours)

Phase 2: Intervention Groups (5-10 participants): Total of 13 visits (19.5 hours)
Groups will be held in the evenings to accommodate work schedules

- Health Education
- Stress Management
  1 time weekly for 13 weeks (approximately 3 months)
- Meditation
  1 introductory meeting
  1 personal interview, followed by 3 daily visits for follow-up
  every other week for 4 months

Phase 3: Post-Intervention Follow-up

- Follow-up Medical History (1 hour)
- Follow-up stress test/blood draw (if applicable)
  (1-2 hours)

Take a day to put the "Silent Killer" to rest!!!

Morehouse School of Medicine
Department of Family Medicine

MANAGING MULTIPLE RISK FACTORS FOR CARDIOVASCULAR DISEASE

DAMD17-95-C-5067

APPENDIX H

MOREHOUSE SCHOOL OF MEDICINE
Dept. of Family Medicine - Behavioral Medicine Research Center
PRELIMINARY SCREENING FOR HEAD-SMART

MMRF ☐
S&A ☐

DATE:_____

GENDER: FEMALE ___ MALE ___ AGE: _____

NAME:_____

ADDRESS:_____
(street number)

_____
(city/state/zip)

PHONE NUMBER (S): (HOME) _____ (WORK) _____

BEST NUMBER TO CONTACT: HOME ☐ WORK ☐ EITHER ☐
BEST TIME TO CALL:

WEIGHT (lbs) _____ HEIGHT (ft/in)_____ RACE: _____

CIRCLE THE NUMBER THAT BEST REPRESENT YOUR *STRESS* LEVEL:

1 2 3 4 5 6 7 8 9 10

LITTLE/ NONE — MODERATE — HIGH

Please check the appropriate answer for the following questions:

- Do you have Diabetes? Yes ☐ No ☐
- Do you smoke? Yes ☐ No ☐
- Do you exercise 3 times a week for at least 20 minutes? Yes ☐ No ☐
- Do you eat a lot of salty foods? Yes ☐ No ☐
- Do you consume more than 2oz of alcohol per day (i.e. more than 4 beers; more than 2 glasses of wine; or more than 2 shots of whiskey)? Yes ☐ No ☐
- Do you have high cholesterol? Yes ☐ No ☐ Don't Know ☐
- Are you currently on medication for high blood pressure? Yes ☐ No ☐
- (Women only) Are you pregnant? Yes ☐ No ☐

Have any members of your **immediate family** (i.e.- mother, father sister, brother, or children) ever had high blood pressure, heart attack, stroke, diabetes or chest pains? Yes ☐ No ☐

Please indicate if you have had any of the following:

Heart Attack	Yes ☐	No ☐
Stroke	Yes ☐	No ☐
Kidney disease	Yes ☐	No ☐
Heart Failure	Yes ☐	No ☐
Abnormal Rhythm of Heart	Yes ☐	No ☐
Any Vascular Disease	Yes ☐	No ☐

Other (Please Specify) _____

STAFF USE ONLY

CURRENT BLOOD PRESSURE READING (S) - *RIGHT ARM.* NOTE: If BP1 is ≥ 130/85 Take 2 more readings.

BP1 _____ BP2 _____ BP3 _____

COMMENTS _____

SCREENING SITE:_____ STAFF INITIALS _____

C:\LNGSCRFRM.WP

BLOOD PRESSURE READINGS FOR 1ST LAB VISIT

NAME _____ DATE _____

SUBJECT # _____

ID # _____ MMRF (8) or S&A (2)

SYSTOLIC (mmHg)/ DIASTOLE (mmHg)

Arm: Left or Right

First Reading _____

Second Reading _____

Third Reading _____

Average
(2 closest systolic readings) _____

Comments:

BLOOD PRESSURE READINGS FOR MEDICAL INTERVIEW (MI)

NAME _____ DATE _____

SUBJECT # _____

ID # _____ MMRF (8) or S&A (2)

SYSTOLIC (mmHg)/ DIASTOLE (mmHg)

Arm: Left or Right

First Reading _____

Second Reading _____

Third Reading _____

Average _____
(2 closest systolic readings)

Comments:

MEDICAL HISTORY

Patient Code: _____ Date: ___/___/___ Staff Initials: _____

Thank you for your interest in the Health Education And Diet/Stress Management Anger Reduction Therapies for African-Americans project at the Behavioral Medicine Research Center. Please fill out this form as completely as you can. If there are questions that you cannot fill out, we will go over them with you when you return. Thank you very much.

First Name _____ Last Name: _____

Street Number and Address: _____ Apt.: _____

City: _____ State: _____ Zip Code: _____

Phone Number (Home): _____ Phone Number (Work): _____

Please provide information for someone who will always know how to reach you in the space below:

Contact Person: _____

Phone Number: _____

Address: _____

_____

MEDICAL HISTORY (cont)

Patient Code: Initials:

Social Security Number: Age: Date of Birth:

State/County of Birth?

How were you referred to the Behavioral Medicine Research Center?

Gender:□Male □Female

Status: □Married □Widowed □Divorced/Separated □Never Married □Living Together

Household Income: □Less than $10,000/yr □$10,000 - $19,999/yr □$20,000 - $50,000/yr □More than $50,000/yr

Occupation:

# of children:

# of children living in household:

Education:

□Grade School
□Some High School
□High School Graduate
□Some College
□College Graduate
□Advanced Degree

Please check if at least 50% of your efforts are spent in the following roles: ***(Check all that apply)***

□A primary financial provider for household
□A primary caretaker of children in the home
□A primary caretaker of adult relative/friend
□A primary financial provider for someone outside of the home
□A primary domestic caretaker for household (ie, chores, cooking)
□Community activist or leader (ie, church/service org., volunteer)

Military Service: □Yes □No Dates of Service:

Status: □Active Duty □Reserve

Branch: □Army □ Navy □Air Force □Marines □Air National Guard □Army National Guard

MEDICAL HISTORY (cont)

Patient Code: _____ Initials: _____

A. Has a doctor ever told you that you had hypertension?
□Yes □No If yes, when (year diagnosed)? _____

B. Have you ever been prescribed medication for high blood pressure? □Yes □No

C. Are you currently taking medication for high blood pressure? □Yes □No

D. How many medications for high blood pressure are you taking? _____

E. List medications in spaces provided below.

Antihypertensive Medication:_____
Prescribed Dose/Frequency:_____
What are you actually taking?:_____
_____

Antihypertensive Medication:_____
Prescribed Dose/Frequency: _____
What are you actually taking?:_____
_____

Antihypertensive Medication:_____
Prescribed Dose/Frequency: _____
What are you actually taking?:_____
_____

MEDICAL HISTORY (cont)

Patient Code: _____ Initials: _____

F. Please write below all other prescribed medications which you are currently taking for **(conditions other than high blood pressure)**:

For what condition are you taking medication? _____
Medication: _____
Prescribed Dose/Frequency: _____
What are you actually taking?: _____

For what condition are you taking medication? _____
Medication: _____
Prescribed Dose/Frequency: _____
What are you actually taking?: _____

For what condition are you taking medication? _____
Medication: _____
Prescribed Dose/Frequency: _____
What are you actually taking?: _____

For what condition are you taking medication? _____
Medication: _____
Prescribed Dose/Frequency: _____
What are you actually taking?: _____

Do you use any herbs or home remedies? □Yes □No

Please list herbs/home remedies used and for what purpose:

CV RISK FACTOR SCREENING

Patient Code: _____ Initials: _____ Age: _____ Gender: ___ (M) ___ (F)

Have any members of your immediate family (mother (M), father (F), sisters (S), brothers (B), or children (C) ever had any of the following? (Indicate only if occurred in women under age 65 and men under age 55).

	M	F	B	S	C
Heart Attack:	☐	☐	☐	☐	☐
Stroke:	☐	☐	☐	☐	☐
High Blood Pressure:	☐	☐	☐	☐	☐
Heart or Chest Pain (Angina):	☐	☐	☐	☐	☐
Diabetes:	☐	☐	☐	☐	☐
Cancer:	☐	☐	☐	☐	☐

HEALTH BEHAVIOR
(Pre-Test)

In the following section we will be asking you a series of questions pertaining to your health and lifestyle. Please be as honest as possible when answering these questions.

A. Rest & Relaxation

1. How many hours each night on average do you sleep? _____

2. How much time do you spend **each day** on average engaging in restful or relaxing activities? Hours/day during week: _____ Hours/day during weekend: _____

3. What do you usually do for relaxation or recreation? _____
_____

4. Do you practice any form of deep relaxation, meditation, prayer, etc.? ☐Yes ☐No

5. If yes, what do you practice? _____

   A. How often do you engage in this activity?

   *Once/week or less _____
   *2-3/week _____
   *4-5/week _____
   *Every day _____
   *More than once/day _____

6. If you practiced meditation or some form of relaxation in the past, but are not doing it now, how long ago did you stop? _____

Now I am going to ask you a series of questions about the foods you eat and about your weight.

B. Diet & Weight

1. Do you drink coffee? ☐Yes ☐No

2. If yes, how many cups of coffee do you drink a day? _____

3. Do you drink tea? ☐Yes ☐No

4. If yes, how many cups of tea do you drink a day? _____

5. Do you eat red meat? ☐Yes ☐No
   a. chicken? ☐Yes ☐No
   b. fish? ☐Yes ☐No
   c. fruits? ☐Yes ☐No
   d. vegetables? ☐Yes ☐No

6. Do you use salt/sodium on your food? ☐Yes ☐No

7. Which of the following best describes how you see yourself?

   a. Slightly overweight _____
   b. Very overweight _____
   c. About average for my height _____
   d. Slightly underweight _____
   e. Very underweight _____

C. Physical Activity/Exercise

During the average week, how much time do you spend on the following activities

	Weekday hours/day	Weekend hours/day
1. **Vigorous Activity** (digging in the garden, jogging, etc.)	_____	_____
2. **Moderate Activity** (housework, light sports, walking, etc.)	_____	_____
3. **Light Activity** (sitting, driving, eating, personal care etc.)	_____	_____
4. **Sleeping** (lying in bed with eyes closed, sleeping in chair, etc.).	_____	_____
Total of each day should =	**24 hours**	**24 hours**

5. **At least once a week**, do you engage in any regular activity akin to brisk walking, jogging, etc., long enough to work up a sweat?
Weekday (Hours/day) _____ Weekend (Hours/day) _____

If yes:

A. How often?

1. Once/week or less _____
2. 2-3/week _____
3. 4 or more times/week _____

B. What type of activity? _____

6. Compared to other people your age, how would you describe your level of physical activity? Would you say that you are...

a. Much more physically active _____
b. Somewhat more active _____
c. Somewhat less active _____
d. Much less active _____
e. Don't know _____

D. Smoking

1. Do you smoke cigarettes? □Yes □No

(If yes, skip to Q. 3)

2. If no, did you ever smoke? □Yes □No

(If no, skip to alcohol, section E)

a. If yes, how many cigarettes did you smoke in an average day? _____
b. How long were you a smoker? _____
c. Did you ever try nicotine gum or one of the nicotine patches? □Yes □ No

(SMOKERS ONLY)

3. How many cigarettes do you smoke now on average each day? _____

4. If you smoke less than one cigarette/day, how many do you smoke in an average week? _____

5. Did you ever try nicotine gum or one of the nicotine patches? □Yes □No

E. Alcohol

1. Do you drink alcohol now? □Yes □No

2. If yes, how much alcohol do you drink each day on average?

		Weekdays	Weekends
a.	No. of beers	_____	_____
b.	No. of glasses of wine	_____	_____
c.	No. of shots of hard liquor	_____	_____

d. If less than one drink per day, how many drinks on average do you drink per week? _____

e. If less than one drink per week, then how often do you drink?

_____

(GO TO Q4)

3. If no, did you ever drink? □Yes □No

(IF NO, SKIP TO NEXT SECTION ON DRUGS)

4. If yes, did you ever drink but then completely quit? □Yes □No
(IF NO, GO TO QUESTION 5)

a. How much did you usually drink each week? _____

b. How many years did you drink? _____

c. When did you quit drinking? _____

5. When you were drinking, were there ever any problems related to your drinking: (CHECK ALL THAT APPLY)

a. At home? □Yes □No
b. At work? □Yes □No
c. With the law? □Yes □No
d. With your health? □Yes □No

F. Recreational Drugs

1. Do you currently use any recreational drugs? □Yes □No

   (IF YES, SKIP TO Q3)

2. If no, did you ever use drugs? □Yes □No

   (IF NO, STOP HERE)

3. If yes, which drugs did you usually use? _____
   _____

4. Did you ever try to quit using drugs? □Yes □No

5. How often did you use drugs each week on average?

   □ Every day
   □ 4-5/week
   □ 2-3/week
   □ Once/week or less
   If less than once/week, how often? _____

6. How many years did you use drugs? _____

7. When you were taking drugs, were there ever any problems related to your taking drugs: (CHECK ALL THAT APPLY)

   a. At home? □Yes □No
   b. At work? □Yes □No
   c. With the law? □Yes □No
   d. With your health? □Yes □No

GH (SF - 36):

In general, would you say your health is:

Excellent Very Good Good Fair Poor

On average, how often do you visit a doctor for regular check-ups?

- ☐ Less than once a year
- ☐ Once a year
- ☐ Twice a year (once every six months)
- ☐ Three times a year (once every four months)
- ☐ Once every 2 - 3 months
- ☐ Once a month
- ☐ Less than once a month

Body Symptoms

Instructions: Please indicate how often you experience each of these symptoms during the **past 4 months** by circling the appropriate number below.

		Not At All	A Little Bit	Quite A Bit	Extremely
1.	Pains behind the eyes	A	B	C	D
2.	Lightheaded	A	B	C	D
3.	Heart feels like it's skipping a beat or two	A	B	C	D
4.	Shakiness	A	B	C	D
5.	Perspires a lot	A	B	C	D
6.	Feel your heart get jumpy	A	B	C	D
7.	Diarrhea	A	B	C	D
8.	Hard to wake up in the morning	A	B	C	D
9.	Sleeping more than usual	A	B	C	D
10.	Bloated	A	B	C	D
11.	Craved certain foods (such as chocolate, etc.)	A	B	C	D

WOMEN ONLY

12.	Abdominal or stomach pains or cramps	A	B	C	D
13.	Breast tenderness or swelling	A	B	C	D
14.	P.M.S.	A	B	C	D

SCL-90-R

Name:_____ Technician: _____ Id. No. _____

Location:_____ Visit No.: _____ Mode: S-R _____ Nar _____

Age: ____ Sex: ____(M) ____(F) Date: _____ Remarks: _____

INSTRUCTIONS

Below is a list of problems and complaints that people sometimes have. Read each one carefully, and select one of the numbered descriptors that best describes HOW MUCH DISCOMFORT THAT PROBLEM HAS CAUSED YOU DURING THE PAST 4 months INCLUDING TODAY. Circle that number to the right of the problem. Do not skip any items and if you have any questions please ask the technician.

	Not At All	A little bit	Moderately	Quite a bit	Extremely
1. Headaches	0	1	2	3	4
2. Nervousness or shakiness inside	0	1	2	3	4
3. Repeated unpleasant thoughts that won't leave your mind	0	1	2	3	4
4. Faintness or dizziness	0	1	2	3	4
5. Loss of sexual interest or pleasure	0	1	2	3	4
6. Feeling critical of others	0	1	2	3	4
7. The idea that someone else can control your thoughts	0	1	2	3	4
8. Feeling others are to blame for most of your troubles	0	1	2	3	4
9. Trouble remembering things	0	1	2	3	4
10. Worried about sloppiness or carelessness	0	1	2	3	4
11. Feeling easily annoyed or irritated	0	1	2	3	4
12. Pains in heart or chest	0	1	2	3	4
13. Feeling afraid in open spaces or on the streets	0	1	2	3	4
14. Feeling low in energy or slowed down	0	1	2	3	4
15. Thoughts of ending your life	0	1	2	3	4
16. Hearing voices that other people do not hear	0	1	2	3	4

SCL-90-R (cont)

INSTRUCTIONS

Below is a list of problems and complaints that people sometimes have. Read each one carefully, and select one of the numbered descriptors that best describes HOW MUCH DISCOMFORT THAT PROBLEM HAS CAUSED YOU DURING THE PAST 4 months INCLUDING TODAY. Circle that number to the right of the problem. Do not skip any items and if you have any questions please ask the technician.

	Not At All	A little bit	Moderately	Quite a bit	Extremely
17. Trembling	0	1	2	3	4
18. Feeling that most people cannot be trusted	0	1	2	3	4
19. Poor appetite	0	1	2	3	4
20. Crying easily	0	1	2	3	4
21. Feeling shy or uneasy with the opposite sex	0	1	2	3	4
22. Feelings of being trapped or caught	0	1	2	3	4
23. Suddenly scared for no reason	0	1	2	3	4
24. Temper outbursts that you could not control	0	1	2	3	4
25. Feeling afraid to go out of your house alone	0	1	2	3	4
26. Blaming yourself for things	0	1	2	3	4
27. Pains in lower back	0	1	2	3	4
28. Feeling blocked in getting things done	0	1	2	3	4
29. Feeling lonely	0	1	2	3	4
30. Feeling blue	0	1	2	3	4
31. Worrying too much about things	0	1	2	3	4
32. Feeling no interest in things	0	1	2	3	4
33. Feeling fearful	0	1	2	3	4
34. Your feelings being easily hurt	0	1	2	3	4
35. Other people being aware of your private thoughts	0	1	2	3	4
36. Feeling others do not understand you or are unsympathetic	0	1	2	3	4
37. Feeling that people are unfriendly or dislike you	0	1	2	3	4

SCL-90-R (cont)

INSTRUCTIONS

Below is a list of problems and complaints that people sometimes have. Read each one carefully, and select one of the numbered descriptors that best describes HOW MUCH DISCOMFORT THAT PROBLEM HAS CAUSED YOU DURING THE PAST 4 months INCLUDING TODAY. Circle that number to the right of the problem. Do not skip any items and if you have any questions please ask the technician.

	Not At All	A little bit	Moderately	Quite a bit	Extremely
38. Having to do things very slowly to Insure correctness	0	1	2	3	4
39. Heart pounding or racing	0	1	2	3	4
40. Nausea or upset stomach	0	1	2	3	4
41. Feeling inferior to others	0	1	2	3	4
42. Soreness of your muscles	0	1	2	3	4
43. Feeling that you are watched or talked about by others	0	1	2	3	4
44. Trouble falling asleep	0	1	2	3	4
45. Having to check and double check what you do	0	1	2	3	4
46. Difficulty making decisions	0	1	2	3	4
47. Feeling afraid to travel on buses, subways, or trains	0	1	2	3	4
48. Trouble getting your breath	0	1	2	3	4
49. Hot or cold spells	0	1	2	3	4
50. Having to avoid certain things, places, or activities because they frighten you	0	1	2	3	4
51. Your mind going blank	0	1	2	3	4
52. Numbness or tingling in parts of your body	0	1	2	3	4
53. A lump in your throat	0	1	2	3	4
54. Feeling hopeless about the future	0	1	2	3	4
55. Trouble concentrating	0	1	2	3	4
56. Feeling weak in parts of your body	0	1	2	3	4
57. Feeling tense or keyed up	0	1	2	3	4
58. Heavy feelings in your arms or legs	0	1	2	3	4
59. Thoughts of death or dying	0	1	2	3	4

SCL-90-R (cont)

INSTRUCTIONS

Below is a list of problems and complaints that people sometimes have. Read each one carefully, and select one of the numbered descriptors that best describes HOW MUCH DISCOMFORT THAT PROBLEM HAS CAUSED YOU DURING THE PAST 4 months INCLUDING TODAY. Circle that number to the right of the problem. Do not skip any items and if you have any questions please ask the technician.

	Not At All	A little bit	Moderately	Quite a bit	Extremely
60. Overeating	0	1	2	3	4
61. Feeling uneasy when people are watching or talking about you	0	1	2	3	4
62. Having thoughts that are not your own	0	1	2	3	4
63. Having urges to beat, injure, or harm someone	0	1	2	3	4
64. Awakening in the early morning	0	1	2	3	4
65. Having to repeat the same actions such as touching, counting, washing	0	1	2	3	4
66. Sleep that is restless or disturbed	0	1	2	3	4
67. Having urges to break or smash things	0	1	2	3	4
68. Having ideas or beliefs that others do not share	0	1	2	3	4
69. Feeling very self-conscious with others	0	1	2	3	4
70. Feeling uneasy in crowds, such as shopping or at a movie	0	1	2	3	4
71. Feeling everything is an effort	0	1	2	3	4
72. Spells of terror or panic	0	1	2	3	4
73. Feeling uncomfortable about eating or drinking in public	0	1	2	3	4
74. Getting into frequent arguments	0	1	2	3	4
75. Feeling nervous when you are left alone	0	1	2	3	4
76. Others not giving you proper credit for your achievements	0	1	2	3	4
77. Feeling lonely even when you are with people	0	1	2	3	4
78. Feeling so restless you couldn't sit still	0	1	2	3	4
79. Feelings of worthlessness	0	1	2	3	4

SCL-90-R (cont)

INSTRUCTIONS

Below is a list of problems and complaints that people sometimes have. Read each one carefully, and select one of the numbered descriptors that best describes HOW MUCH DISCOMFORT THAT PROBLEM HAS CAUSED YOU DURING THE PAST 4 months INCLUDING TODAY. Circle that number to the right of the problem. Do not skip any items and if you have any questions please ask the technician.

	Not At All	A little bit	Moderately	Quite a bit	Extremely
80. The feeling that something bad is going to happen to you	0	1	2	3	4
81. Shouting or throwing things	0	1	2	3	4
82. Feeling afraid you will faint in public	0	1	2	3	4
83. Feeling that people will take advantage of you if you let them	0	1	2	3	4
84. Having thoughts about sex that bother you a lot	0	1	2	3	4
85. The idea that you should be punished for your sins	0	1	2	3	4
86. Thoughts and images of a frightening nature	0	1	2	3	4
87. The idea that something serious is wrong with your body	0	1	2	3	4
88. Never feeling close to another person	0	1	2	3	4
89. Feelings of guilt	0	1	2	3	4
90. The idea that something is wrong with your mind	0	1	2	3	4

SI:

1. Over the past month or so, how often have you had health problems?

Always	Very Often	Fairly Often	Sometimes	Almost Never	Never
1	2	3	4	5	6

2. Over the past month or so, how often have you had money problems?

Always	Very Often	Fairly Often	Sometimes	Almost Never	Never
1	2	3	4	5	6

3. Over the past month or so, how often have you had problems with your family (spouse, children, or grandchildren)?

Always	Very Often	Fairly Often	Sometimes	Almost Never	Never
1	2	3	4	5	6

4. Over the past month or so, how often have you had problems with people outside your family?

Always	Very Often	Fairly Often	Sometimes	Almost Never	Never
1	2	3	4	5	6

5. Have you been employed during the last month? □Yes □No
   If yes: How much demand or pressure were you under at work?

A Great Deal	Very Much	A Lot	Some	Just a Little	None
1	2	3	4	5	6

6. If no: How often did you have problems due to being unemployed during the past month?

A Great Deal	Very Much	A Lot	Some	Just a Little	None
1	2	3	4	5	6

7. Over the past month or so, how much demand or pressure were you under at home?

A Great Deal	Very Much	A Lot	Some	Just a Little	None
1	2	3	4	5	6

PERCEIVED STRESS SCALE:HOME

Instructions: The questions in this scale ask you about your feelings and thoughts during the last month while you were at home. In each case, you will be asked to indicate how often you felt or thought a certain way. Although some of the questions are similar, there are differences between them and you should treat each one as a separate question. The best approach is to answer each question fairly quickly. That is, don't try to count up the number of times you felt a particular way, but rather indicate the alternative that seems like a reasonable estimate.

For each item below, please complete the following statement by circling a number from 1 to 5:

In the last month, how often have you:	Never	Almost Never	Some Times	Fairly Often	Very Often
1. Been upset because of something that happened unexpectedly at home?	1	2	3	4	5
2. Felt that you were unable to control the important things at home?	1	2	3	4	5
3. Felt nervous and "stressed" at home?	1	2	3	4	5
4. Dealt successfully with irritating hassles at home?	1	2	3	4	5
5. Felt that you were effectively coping with important changes that were occurring at home?	1	2	3	4	5
6. Felt confident about your ability to handle your personal problems at home?	1	2	3	4	5
7. Felt that things were going your way at home?	1	2	3	4	5
8. Found that you could not cope with all the things you had to do at home?	1	2	3	4	5
9. Been able to control irritations at home?	1	2	3	4	5
10. Felt that you were on top of things at home?	1	2	3	4	5
11. Been angered because of things that happened at home that were outside of your control?	1	2	3	4	5
12. Found yourself thinking about things at home that you have to accomplish?	1	2	3	4	5
13. Been able to control the way you spend your time at home?	1	2	3	4	5
14. Felt difficulties at home were piling up so high that you could not overcome them?	1	2	3	4	5

PERCEIVED STRESS SCALE: WORK

Instructions: The questions in this scale ask you about your feelings and thoughts during the last month while you were at work. In each case, you will be asked to indicate how often you felt or thought a certain way. Although some of the questions are similar, there are differences between them and you should treat each one as a separate question. The best approach is to answer each question fairly quickly. That is, don't try to count up the number of times you felt a particular way, but rather indicate the alternative that seems like a reasonable estimate.

For each item below, please complete the following statement by circling a number from 1 to 5:

	Almost Never	Never	Some Times	Fairly Often	Very Often
1. Been upset because of something that happened unexpectedly at work?	1	2	3	4	5
2. Felt that you were unable to control important things at work?	1	2	3	4	5
3. Felt nervous and "stressed" at work?	1	2	3	4	5
4. Dealt successfully with irritating hassles at work?	1	2	3	4	5
5. Felt that you were effectively coping with important changes that were occurring at work?	1	2	3	4	5
6. Felt confident about your ability to handle your problems at work?	1	2	3	4	5
7. Felt that things were going your way at work?	1	2	3	4	5
8. Found that you could not cope with all the things you had to do at work?	1	2	3	4	5
9. Been able to control irritations at work?	1	2	3	4	5
10. Felt that you were on top of things at work?	1	2	3	4	5
11. Been angered because of things that happened at work that were outside of your control?	1	2	3	4	5
12. Found yourself thinking about things at work that you have to accomplish?	1	2	3	4	5
13. Been able to control the way you spend your time at work?	1	2	3	4	5
14. Felt difficulties at work were piling up so high that you could not overcome them?	1	2	3	4	5

EMPLOYED ☐Yes ☐No

1. How long at present job? _____

   If unemployed, when did you leave your last job? _____
   Why did you leave your last job? ☐ Company went out of business
   ☐ Laid off
   ☐ Quit
   ☐ Lack of schooling
   ☐ Other (specify) _____

2. How satisfied are you with your present job?

   ☐ Very satisfied
   ☐ Somewhat satisfied
   ☐ Somewhat dissatisfied
   ☐ Very dissatisfied

3. In the last six months, how many times has disciplinary action been given (written up, etc.) in your job? ____

4. In the last six months, how often have you been late/tardy to work? _____

5. How would you rate your job performance?

   ☐ Excellent
   ☐ Good
   ☐ Satisfactory
   ☐ Somewhat dissatisfactory
   ☐ Dissatisfactory

6. In your last review, how did your boss rate your performance? **(If no formal review process, GO TO NUMBER 7)**

   ☐ Excellent
   ☐ Good
   ☐ Satisfactory
   ☐ Somewhat dissatisfactory
   ☐ Dissatisfactory
   ☐ No formal review

7. How do you think your boss would rate your performance?

   ☐ Excellent
   ☐ Good
   ☐ Satisfactory
   ☐ Somewhat dissatisfactory
   ☐ Dissatisfactory

8. How many days have you taken off in the last year? _____

9. How many of those days due to sick leave? _____

10. How would you feel if a son/daughter of yours had your job on a regular, permanent basis?

- ☐ Very satisfied
- ☐ Somewhat satisfied
- ☐ Somewhat dissatisfied
- ☐ Very dissatisfied

11. In general, how likely would you be to leave your current job for a similar position with different work conditions?

- ☐ Very likely
- ☐ Somewhat likely
- ☐ Somewhat unlikely
- ☐ Very unlikely

12. How satisfied are you with current work relationships?

- ☐ Very satisfied
- ☐ Somewhat satisfied
- ☐ Somewhat dissatisfied
- ☐ Very dissatisfied

13. How often do you socialize with co-workers?

- ☐ Never
- ☐ Almost never
- ☐ Sometimes
- ☐ Fairly often
- ☐ Very often

14. How would you characterize relationships with your co-workers?

- ☐ Very friendly
- ☐ Somewhat friendly
- ☐ Neither friendly nor hostile
- ☐ Somewhat hostile
- ☐ Very hostile

NBSASS:

1. If you needed money for rent, food, or clothes, are there any people you could count on for help with these expenses?

   □Yes □No

2. If you needed help with babysitting, transportation or other non-financial situations, are there people you could count on for help?

   □Yes □No

   a. Are they mostly relatives or friends?

   □ Relatives
   □ Friends
   □ Both

   b. Which relatives help you the most?

   □ Child
   □ Niece/Nephew
   □ Siblings (brother/sister)
   □ Aunts/Uncles
   □ Parent
   □ Grandparent
   □ Other (specify) _____

   c. In the past year, how often have others tried helping you with these expenses? Would you say...

   □ Very often
   □ Fairly often
   □ Not too often
   □ Never

3. If things got so bad that you could not support yourself at all, is there anyone you could live with?

   □Yes □No

   a. If that happened, who would you most likely live with?

   □ Friend
   □ Child
   □ Niece/Nephew
   □ Siblings (brother/sister)
   □ Aunts/Uncles
   □ Parent
   □ Grandparent
   □ Other (specify) _____

   b. Would your moving in with them place any hardship on them?

   □Yes □No

Interpersonal Behavior Scale
Part A

Instructions: A number of statements are listed below which people have used to describe their interactions with others. Read each statement and then circle the appropriate number to indicate how often you generally react in the manner described. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe how you generally react.

		Almost Never	Some Times	Often	Almost Always
1.	I try to do what is sensible and logical	1	2	3	4
2.	I try to understand people and their behavior	1	2	3	4
3	I try to behave reasonable in my relations with others	1	2	3	4
4.	I use intelligence and reason to overcome conflicts or disagreements with other people	1	2	3	4
5.	When I am in a situation in which I strongly disagree with other people, I try not to show my emotions	1	2	3	4
6.	If someone deeply hurts my feelings, I still try to treat them reasonably and to understand their behavior	1	2	3	4
7.	I try to understand other people even if I do not like them	1	2	3	4
8.	I succeed in avoiding arguments with others by using reason and logic (often contrary to my feelings)	1	2	3	4
9.	If someone acts against my needs and desires, I still try to understand him/her	1	2	3	4
10.	My behavior in most life situations is logical and reasonable, and not influenced by my emotions	1	2	3	4
11.	If someone deeply hurts my feelings, I may attack them or respond purely emotionally	1	2	3	4
12.	My use of reason and logic prevents me from attacking others, even if there are good reasons for doing so	1	2	3	4

Interpersonal Behavior Scale
Part B

Instructions: A number of statements are listed below which people have used to describe their interactions with others. Read each statement and then circle the appropriate number to indicate how often you generally react in the manner described. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe how you generally react.

		Almost Never	Some Times	Almost Often	Always
1.	I will accept difficulties and ignore my own needs in order to have harmonious (peaceful) relationships with others	1	2	3	4
2.	My aim in life is to live for my dearest friends and my family members, without demanding anything for myself	1	2	3	4
3.	I am available to help someone I care about with even the smallest problem	1	2	3	4
4.	I want to have only harmonious (peaceful) relations with my best friend	1	2	3	4
5.	When I care about someone I go out of my way to make that person happy	1	2	3	4
6.	I am willing to make personal sacrifices to maintain smooth relationships with people I care about	1	2	3	4
7.	It is important for me to do everything possible to have harmonious (peaceful) relationships with people I care about	1	2	3	4
8.	When I can't be with my closest friends, I enjoy talking with them on the phone	1	2	3	4
9.	It is very important to me to make my dear ones happy	1	2	3	4
10.	When there is a conflict between my own needs and taking care of someone important to me, I will sacrifice my own needs to help the other person	1	2	3	4
11.	I feel responsible for making my relationships with others go as smoothly as possible	1	2	3	4
12.	It is very important to me to get along perfectly with people who are dear to me	1	2	3	4

The J H Scale

Instructions: Please circle the answer that best describes you and your behavior.

		Not True	Somewhat True	Very True
1.	I've always felt that I could make of my life pretty much what I wanted to make of it	1	2	3
2.	Once I make up my mind to do something, I stay with it until the job is completely done	1	2	3
3.	I don't let my personal feelings get in the way of getting a job done	1	2	3
4.	It's important for me to be able to do things in the way I want to do them rather than in the way other people want me to do them	1	2	3
5.	Sometimes I feel that if anything is going to be done right, I have to do it myself	1	2	3
6.	I like doing things that other people thought could not be done	1	2	3
7.	I feel that I am the kind of person who stands up for what I believe in, regardless of the consequences	1	2	3
8.	Hard work is the best possible way for a person to get ahead in life	1	2	3

COPE INVENTORY

These items ask what you've been doing to cope with stress. Obviously, different people deal with things in different ways, but I'm interested in how you've tried to deal with it. Each item says something about a particular way of coping. I want to know *to what extent* you've been doing what the item says - how *much* or how *frequently*. Don't answer on the basis of whether it seems to be *working* or not--just whether or not you're doing it. Use these response choices. Try to rate each item separately in your mind from the others. Make your answers as true FOR YOU as you can.

		Not At All	A Little Bit	A Medium Amount	A Lot
1.	I've been turning to work or other activities to take my mind off things.	1	2	3	4
2.	I've been concentrating my efforts on doing something about the situation I'm in.	1	2	3	4
3.	I've been saying to myself this isn't real.	1	2	3	4
4.	I've been using alcohol or other drugs to make myself feel better.	1	2	3	4
5.	I've been getting emotional support from others.	1	2	3	4
6.	I've been giving up trying to deal with it.	1	2	3	4
7.	I've been taking action to try to make the situation better.	1	2	3	4
8.	I've been refusing to believe that it has happened.	1	2	3	4
9.	I've been saying things to let my unpleasant feelings escape.	1	2	3	4
10.	I've been getting help and advice from other people.	1	2	3	4
11.	I've been using alcohol or other drugs to help me get through it.	1	2	3	4
12.	I've been trying to see it in a different light, to make it seem more positive.	1	2	3	4
13.	I've been criticizing myself.	1	2	3	4
14.	I've been trying to come up with a strategy about what to do.	1	2	3	4
15.	I've been getting comfort and understanding from someone.	1	2	3	4
16.	I've been giving up the attempt to cope.	1	2	3	4
17.	I've been looking for something good in what is happening.	1	2	3	4
18.	I've been making jokes about it.	1	2	3	4

COPE INVENTORY

These items ask what you've been doing to cope with stress. Obviously, different people deal with things in different ways, but I'm interested in how you've tried to deal with it. Each item says something about a particular way of coping. I want to know *to what extent* you've been doing what the item says - how *much* or how *frequently*. Don't answer on the basis of whether it seems to be *working* or not--just whether or not you're doing it. Use these response choices. Try to rate each item separately in your mind from the others. Make your answers as true FOR YOU as you can.

		Not At All	A Little Bit	A Medium Amount	A Lot
19.	I've been doing something to think about it less, such as going to movies, watching TV, reading, daydreaming, sleeping, or shopping.	1	2	3	4
20.	I've been accepting the reality of the fact that it has happened.	1	2	3	4
21.	I've been expressing my negative feelings.	1	2	3	4
22.	I've been trying to find comfort in my religion or spiritual beliefs.	1	2	3	4
23.	I've been trying to get advice or help from other people about what to do.	1	2	3	4
24.	I've been learning to live with it.	1	2	3	4
25.	I've been thinking hard about what steps to take.	1	2	3	4
26.	I've been blaming myself for things that happened.	1	2	3	4
27.	I've been praying or meditating.	1	2	3	4
28.	I've been making fun of the situation	1	2	3	4

STAXI
Part I

Directions: A number of statements that people use to describe themselves are given below. Read each statement and then circle the appropriate number to indicate how you feel right now. There are no right or wrong answers. Do not spend too much time on any one statement, but give the answer which seems to best describe your present feelings.

		Not at all	Somewhat	Moderately So	Very much so
1.	I am furious	1	2	3	4
2.	I feel irritated	1	2	3	4
3.	I feel angry	1	2	3	4
4.	I feel like yelling at somebody	1	2	3	4
5.	I feel like breaking things	1	2	3	4
6.	I am mad	1	2	3	4
7.	I feel like banging on the table	1	2	3	4
8.	I feel like hitting someone	1	2	3	4
9.	I am burned up	1	2	3	4
10.	I feel like swearing	1	2	3	4

STAXI
Part II

Directions: A number of statements that people use to describe themselves are given below. Read each statement and then circle the appropriate number to indicate how you generally feel. There are no right or wrong answers. Do not spend too much time on any one statement, but give the answer which seems to best describe how you generally feel.

		Almost Never	Sometimes	Often	Almost Always
11.	I am quick tempered	1	2	3	4
12.	I have a quick temper	1	2	3	4
13.	I am a hotheaded person	1	2	3	4
14.	I get angry when I'm slowed down by others' mistakes	1	2	3	4
15.	I feel annoyed when I am not given recognition for doing good work	1	2	3	4
16.	I fly off the handle	1	2	3	4
17.	When I get mad, I say nasty things	1	2	3	4
18.	It makes me furious when I am criticized in front of others	1	2	3	4
19.	When I get frustrated, I feel like hitting someone	1	2	3	4
20.	I feel infuriated when I do a good job and get a poor evaluation	1	2	3	4

STAXI
Part III

Directions: Everyone feels angry or furious from time to time, but people differ in the ways that they react when they are angry. A number of statements are listed below which people use to describe their reactions when they feel angry or furious. Read each statement and then circle the appropriate number to indicate how often you generally react or behave in the manner described when you are feeling angry or furious. There are no right or wrong answers. Do not spend too much time on any one statement.

		Almost Never	Sometimes	Often	Almost Always
WHEN ANGRY OR FURIOUS,					
21.	I control my temper	1	2	3	4
22.	I express my anger	1	2	3	4
23.	I keep things in	1	2	3	4
24.	I am patient with others	1	2	3	4
25.	I pout or sulk	1	2	3	4
26.	I withdraw from people	1	2	3	4
27.	I make sarcastic remarks to others	1	2	3	4
28.	I keep my cool	1	2	3	4
29.	I do things like slam doors	1	2	3	4
30.	I boil inside, but I don't show it	1	2	3	4
31.	I control my behavior	1	2	3	4
32.	I argue with others	1	2	3	4
33.	I tend to harbor grudges that I don't tell anyone about	1	2	3	4

STAXI
Part III (cont)

Directions: Everyone feels angry or furious from time to time, but people differ in the ways that they react when they are angry. A number of statements are listed below which people use to describe their reactions when they feel angry or furious. Read each statement and then circle the appropriate number to indicate how often you generally react or behave in the manner described when you are feeling angry or furious. There are no right or wrong answers. Do not spend too much time on any one statement.

		Almost Never	Sometimes	Often	Almost Always
34.	I strike out at whatever infuriates me	1	2	3	4
35.	I can stop myself from losing my temper	1	2	3	4
36.	I am secretly quite critical of others	1	2	3	4
37.	I am angrier than I am willing to admit	1	2	3	4
38.	I calm down faster than most other people	1	2	3	4
39.	I try to be tolerant and understanding	1	2	3	4
40.	I'm irritated a great deal more than people are aware of	1	2	3	4
41.	I lose my temper	1	2	3	4
42.	If someone annoys me, I'm apt to tell him or her how I feel	1	2	3	4
43.	I control my angry feelings	1	2	3	4
44.	I say nasty things	1	2	3	4

Statements 1-60 describe things that people sometimes think, feel, and do. How true are they for you? For each statement, circle the number to indicate whether that statement is (1) never true, (2) sometimes true, or (3) always true for you. Please mark only one response for each statement.

		Never true	Sometimes true	Always true
1.	When something wrong is done to me, I am going to get angry	1	2	3
2.	Once something makes me angry, I keep thinking about it	1	2	3
3.	Every week I meet someone I dislike	1	2	3
4.	I know that people are talking about me behind my back	1	2	3
5.	When something makes me angry, I put it out of my mind and think of something else	1	2	3
6.	Some people would say that I am a hothead	1	2	3
7.	My muscles feel tight and wound up	1	2	3
8.	When I get angry, I stay angry for hours	1	2	3
9.	I walk around in a bad mood	1	2	3
10.	If I feel myself getting angry, I can calm myself down	1	2	3
11.	My temper is quick and hot	1	2	3
12.	When someone yells at me, I yell back at them	1	2	3
13.	I have had to be rough with people who bothered me	1	2	3
14.	I feel like smashing things	1	2	3
15.	When I am frustrated by a problem, I try to find a solution	1	2	3
16.	I get angry because I have a good reason to be angry	1	2	3
17.	I can't sleep when something wrong has been done to me	1	2	3
18.	If I don't like someone, it doesn't bother me to hurt their feelings	1	2	3
19.	People can be trusted to do what they say	1	2	3

Statements 1-60 describe things that people sometimes think, feel, and do. How true are they for you? For each statement, circle the number to indicate whether that statement is (1) never true, (2) sometimes true, or (3) always true for you. Please mark only one response for each statement.

		Never true	Sometimes true	Always true
20.	I try to see positive things in other people	1	2	3
21.	When I get angry, I get really angry	1	2	3
22.	When I think about something that makes me angry, I get even more angry	1	2	3
23.	I feel agitated and unable to relax	1	2	3
24.	I get annoyed when someone interrupts me	1	2	3
25.	I am able to stay cool in the face of pressure	1	2	3
26.	If someone bothers me, I react first and think later	1	2	3
27.	If I don't like somebody, I'll tell them off	1	2	3
28.	When I get mad, I can easily hit someone	1	2	3
29.	When I get angry, I throw or slam things	1	2	3
30.	When I have a conflict with someone, I speak to that person about the problem	1	2	3
31.	If I lose my temper with someone, it's because they deserved it	1	2	3
32.	When someone makes me angry, I think about getting even	1	2	3
33.	If someone cheats me, I'd make them feel sorry	1	2	3
34.	People act like they are being honest when they really have something to hide	1	2	3

Statements 1-60 describe things that people sometimes think, feel, and do. How true are they for you? For each statement, fill in the circle on the right side to indicate whether that statement is (1) never true, (2) sometimes true, or (3) always true for you. Please mark only one response for each statement.

		Never true	Sometimes true	Always true
35.	If someone says something nasty, I can swallow my pride and let it go	1	2	3
36.	When I get angry, I feel like smashing things	1	2	3
37.	Some people get angry and get over it, but for me it takes a long time	1	2	3
38.	I have trouble sleeping or falling asleep	1	2	3
39.	A lot of little things bug me	1	2	3
40.	When I get agitated, I can relax by taking deep breaths	1	2	3
41.	I have a fiery temper that arises in an instant	1	2	3
42.	Some people need to be told to "get lost"	1	2	3
43.	If someone hits me first, I hit them back	1	2	3
[illegible]	When I get angry at someone, I take it out on whomever is around	1	2	3
45.	If I disagree with someone, I try to say something constructive	1	2	3
46.	The more someone bothers me, the more I'll get angry	1	2	3
47.	I feel like I am getting a raw deal out of life	1	2	3
48.	When I don't like somebody, there's no point in being nice to them	1	2	3
49.	When someone does something nice for me, I wonder about the hidden reason	1	2	3
50.	If someone is bothering me, I try to understand why	1	2	3
51.	It makes my blood boil to have someone make fun of me	1	2	3
[illegible]	When I get mad at someone, I give them the silent treatment	1	2	3

Statements 1-60 describe things that people sometimes think, feel, and do. How true are they for you? For each statement, fill in the circle on the right side to indicate whether that statement is (1) never true, (2) sometimes true, or (3) always true for you. Please mark only one response for each statement.

		Never true	Sometimes true	Always true
53.	My head aches when people annoy me	1	2	3
54.	It bothers me when someone does things the wrong way	1	2	3
55.	I can get rid of tension by imagining something calm and relaxing	1	2	3
56.	When I get angry, I fly off the handle before I know it	1	2	3
57.	When I start to argue with someone, I don't stop until they do	1	2	3
58.	Some people need to get knocked around	1	2	3
59.	If someone makes me angry, I'll tell other people about them	1	2	3
60.	I can walk away from an argument	1	2	3

Statements 61-88 describe situations that can make someone angry. Using the scale on the right side, circle the answer that best describes how angry each situation would make you feel: (1) not at all angry, (2) a little angry, (3) fairly angry, or (4) very angry. Please mark only one answer for each statement.

		Not at all angry	A little angry	Fairly angry	Very angry
61.	Being criticized in front of other people for something that you have done	1	2	3	4
62.	You see someone bully another person who is smaller or less powerful	1	2	3	4
63.	Someone keeps making noise when you are trying to concentrate	1	2	3	4
64.	People who act like they know it all	1	2	3	4
65.	Being slowed down by another person's mistakes	1	2	3	4
66.	Someone cuts in front of you when you are in line to get something	1	2	3	4

Statements 61-88 describe situations that can make someone angry. Using the scale on the right side, circle the answer that best describes how angry each situation would make you feel: (1) not at all angry, (2) a little angry, (3) fairly angry, or (4) very angry. Please mark only one answer for each statement.

		Not at all angry	A little angry	Fairly angry	Very angry .
67.	Not being given recognition for doing good work	1	2	3	4
68.	You are watching a TV program, when someone comes along and switches the channel	1	2	3	4
69.	People who don't really listen when you talk to them	1	2	3	4
70.	You get cold food that is supposed to be hot	1	2	3	4
71.	Someone looking over your shoulder while you are working	1	2	3	4
72.	Someone else gets credit for work than you did	1	2	3	4
73.	You put money in a vending machine, but nothing comes out	1	2	3	4
74.	People who think that they are better than you are	1	2	3	4
75.	You are carrying a full lunch tray, and someone bumps into you	1	2	3	4
76.	Someone makes fun of the clothes you are wearing	1	2	3	4
77.	You get singled out for correction, when someone else doing the same thing is ignored	1	2	3	4
78.	You make plans to do something with a person who backs out at the last minute	1	2	3	4
79.	People who think that they are always right	1	2	3	4
80.	Just after waking up in the morning, someone starts giving you a hard time	1	2	3	4

Statements 61-88 describe situations that can make someone angry. Using the scale on the right side, circle the answer that best describes how angry each situation would make you feel: (1) not at all angry, (2) a little angry, (3) fairly angry, or (4) very angry. Please mark only one answer for each statement.

		Not at all angry	A little angry	Fairly angry	Very angry
81.	Someone looks through your things without your permission	1	2	3	4
82.	Being accused of something that you didn't do	1	2	3	4
83.	You lend something to someone, and they fail to return it	1	2	3	4
84.	Someone who is always disagreeing with you	1	2	3	4
85.	You are hungry and tired, and someone plays a practical joke on you	1	2	3	4
86.	You are overcharged by someone for a repair	1	2	3	4
87.	You need to get somewhere in a hurry, but you get stuck in traffic	1	2	3	4
88.	You are carrying a hot drink, and someone bumps into you	1	2	3	4

Think about whether statements 89-121 are true or false for you. Circle T if the statement is true for you, or F if the statement if false. Please mark only one answer for each statement..

		True	False
89.	Before I vote, I find out everything I can about the qualifications of all the candidates	T	F
90.	I never hesitate to go out of my way to help someone in trouble	T	F
91.	It is sometimes hard for me to go on with my work if no one encourages me	T	F
92.	I have never intensely disliked anyone	T	F
93.	At times I have doubted my ability to succeed in life	T	F
94.	Sometimes I resent it when I don't get my way	T	F
95.	I am always careful about the way I dress	T	F

Think about whether statements 89-121 are true or false for you. Circle T if the statement is true for you, or F if the statement if false. Please mark only one answer for each statement..

		True	False
96.	My table manners at home are as good as when I go out to eat	T	F
97.	If I could get into a movie without paying and be sure nobody saw me, I would probably do it	T	F
98.	At times I have given up on something because I thought too little of my ability	T	F
99.	I like to gossip at times	T	F
100.	At times I have wanted to rebel against people in authority, even though I knew they were right	T	F
101.	I am always a good listener, no matter who is talking	T	F
102.	I can remember pretending to be sick in order to get out of doing something	T	F
103.	At times I have taken advantage of another person	T	F
104.	When I have made a mistake, I am always willing to admit it	T	F
105.	I always try to practice what I preach	T	F
106.	I can get along easily with loudmouthed, obnoxious people	T	F
107.	Sometimes I try to get even rather than to forgive and forget	T	F
108.	If I don't know something, it doesn't bother me at all to admit it	T	F
109.	I am always polite, even to disagreeable people	T	F
110.	At times I have insisted on having things my own way	T	F
111.	At times I have felt like smashing things	T	F
112.	I would never even think of letting someone else be punished for something I did	T	F
113.	I never resent being asked to return a favor	T	F
114.	I have never been annoyed when people expressed ideas very different from mine	T	F
115.	I would never make a long trip without checking the safety of my car	T	F
116.	At times I have been quite jealous of someone else's good fortune	T	F

Think about whether statements 89-121 are true or false for you. Circle T if the statement is true for you, or F if the statement if false. Please mark only one answer for each statement..

		True	False
117.	I have almost never wanted to tell someone off	T	F
118.	Sometimes I am irritated by people who ask favors of me	T	F
119.	I have never felt that I was punished without cause	T	F
120.	At times I think that, when something bad happens to someone, they got what they deserved	T	F
121.	I have never said anything that hurt another person's feelings	T	F

COOK-MEDLEY HOSTILITY SCALE

This questionnaire consists of numbered statements. Read each statement and decide whether it is true as applied to you or **false as applied to you**. Write **T** if it is **TRUE** and **F** if it is **FALSE**. Remember to give your own opinion of yourself.

_____1. When someone does me wrong, I feel I should pay him back if I can, just for the principle of the thing.

_____2. I have often had to take orders from someone who did not know as much as I did.

_____3. I think a great many people exaggerate their misfortunes in order to gain the sympathy and help of others.

_____4. It takes a lot of argument to convince most people of the truth.

_____5. I think most people would lie to get ahead.

_____6. Most people are honest chiefly through fear of being caught.

_____7. Most people will use somewhat unfair means to gain profit or an advantage rather than to lose it.

_____8. It makes me impatient to have people ask my advice or otherwise interrupt me when I am working on something important.

_____9. Some of my family have habits that bother and annoy me very much.

_____10. I can be friendly with people who do things which I consider wrong.

_____11. I don't blame anyone for trying to grab everything he can get in this world.

_____12. No one cares much about what happens to you.

_____13. It is safer to trust nobody.

_____14. I do not blame a person for taking advantage of people who leave themselves open to it.

_____15. Most people make friends because friends are likely to be useful to them.

_____16. Most people inwardly dislike putting themselves out to help other people.

_____17. People often disappoint me.

_____18. I have often met people who were supposed to be experts who were no better than I.

_____19. I am not easily angered.

_____20. People generally demand more respect for their own rights than they are willing to allow for others.

_____21. I would certainly enjoy beating criminals at their own game.

_____22. I have at times had to be rough with people who were rude or annoying.

COOK-MEDLEY HOSTILITY SCALE (cont)

This questionnaire consists of numbered statements. Read each statement and decide whether it is **true as applied to you** or **false as applied to you**. Write **T** if it is **TRUE** and **F** if it is **FALSE**. Remember to give your own opinion of yourself.

_____23. There are certain people whom I dislike so much that I am inwardly pleased when they are catching it for something they have done.

_____24. I am often inclined to go out of my way to win a point with someone who has opposed me.

_____25. I do not try to cover up my poor opinion or pity of a person so that he won't know how I feel.

_____26. I strongly defend my opinions as a rule.

_____27. A large number of people are guilty of bad sexual conduct

CSES:

Instructions: Five items are given below. Each item asks you for an opinion about yourself. Please read the statements in each item and CIRCLE THE NUMBER that best describes how you feel about yourself on that dimension. Please be as accurate as possible. Thank you.

1. My self-confidence

9-----Extremely sure of self
8-----Very sure of self
7-----Sure of self
6-----Somewhat sure of self
5-----Average self-assurance
4-----Somewhat unsure of self
3-----Unsure of self
2-----Very unsure of self
1-----Extremely unsure of self

2. Opinion of self

9-----Extremely good
8-----Very good
7-----Good
6-----Somewhat good
5-----Average
4-----Somewhat poor
3-----Poor
2-----Very poor
1-----Extremely poor

3. Self-esteem

9-----Extremely high
8-----Very high
7-----High
6-----Somewhat high
5-----Average
4-----Somewhat low
3-----Low
2-----Very low
1-----Extremely low

4. Satisfaction with self

9-----Extremely satisfied
8-----Very satisfied
7-----Satisfied
6-----Somewhat satisfied
5-----Neutral
4-----Somewhat dissatisfied
3-----Dissatisfied
2-----Very dissatisfied
1-----Extremely dissatisfied

5. Respect for self

9-----Tremendous amount
8-----Very much
7-----Much
6-----Somewhat more than average
5-----Average amount
4-----Somewhat less than average
3-----Little
2-----Very little
1-----Extremely little

Name_____ Subject _____ Date_____ Visit_____

MMRF

Sessions: Post Intervention, 6 month

Walk-in Blood Pressures (1)Systolic _____ /Diastolic_____

(2)Systolic _____ /Diastolic_____

(3)Systolic _____ /Diastolic_____

Average BP Readings _____ /_____ Time BP was Taken_____ a.m. or p.m.

Age_____ Filename_____

Weight_____

Height _____

Gender: M F

Skin Fold Assessment

Biceps_____ mm

Triceps_____ mm

Suprailiac _____ mm

Subscapular_____ mm

Total Skin Folds_____ mm

% of Body Fat_____ mm

Neck Circum._____ cm

Waist_____ cm

Hips_____ cm

(1) Sit quietly for 5 minutes

(a) Start Baseline Measurements

(b) 10 Minute Baseline:

Measurement Time Zero SBP_____ DBP_____ HR_____

FABF_____ R_____

SBP_____ DBP_____ HR_____

FABF_____ R_____

SBP_____ DBP_____ HR_____

FABF_____ R_____

SBP_____ DBP_____ HR_____

FABF_____ R_____

SBP_____ DBP_____ HR_____

Arithmetic test (6 minutes)

SBP_____ DBP_____ HR_____

FABF_____ R_____

SBP_____ DBP_____ HR_____

FABF_____ R_____

SBP_____ DBP_____ HR_____

FABF_____ R_____

SBP_____ DBP_____ HR_____

Rest and Recovery (3 minutes)

SBP_____ DBP_____ HR_____

FABF_____ R_____

Forehead Cold Pressor Test (90sec.)

SBP_____ DBP_____ HR_____

FABF_____ R_____

SBP_____ DBP_____ HR_____

FABF_____ R_____

SBP_____ DBP_____ HR_____

Rest and Recovery (3 minutes)

SBP_____ DBP_____ HR_____

FABF_____ R _____

Conflict Task Readings (BP's taken at 3min., 5min, 8min., and 10min.)

SBP_____ DBP_____ HR_____

FABF_____ R _____

SBP_____ DBP_____ HR_____

FABF_____ R _____

SBP_____ DBP_____ HR _____

FABF_____ R_____

SBP_____ DBP_____ HR _____

Rest and Recovery (20 Minutes; BP's taken at 4min., 8min., 12min., and 16min.)

SBP_____ DBP_____ HR_____

FABF_____ R _____

SBP_____ DBP_____ HR_____

FABF_____ R _____

SBP_____ DBP_____ HR _____

FABF_____ R_____

SBP_____ DBP_____ HR _____

INSTRUCTIONS

Please rate on the 10-point scale below how stressful you found talking about the very upsetting experience you just shared with us.

[_____]
0 1 2 3 4 5 6 7 8 9 10

COMMENTS_____

_____

_____

BLOOD PRESSURE RECORD

Name _____ Subject # _____ Date _____

ID # _____ MMRF (8) or S&A (2)

Filename _____

SYSTOLIC (mmHg)/ DIASTOLIC(mmHg)

Arm: Left or Right
First Reading _____ / _____ Visit # 1 2 3 4 5

Second Reading _____ / _____ Date _____

Third Reading _____ / _____

Average _____ / _____ (2 closest systolic readings)

Arm: Left or Right
First Reading _____ / _____ Visit # 1 2 3 4 5

Second Reading _____ / _____ Date _____

Third Reading _____ / _____

Average _____ / _____ (2 closest systolic readings)

Arm: Left or Right
First Reading _____ / _____ Visit # 1 2 3 4 5

Second Reading _____ / _____ Date _____

Third Reading _____ / _____

Average _____ / _____ (2 closest systolic readings

Averages of all 3 averages _____ / _____

Comments _____

_____

_____

FOLLOW-UP BLOOD PRESSURE RECORD

Name _____ Subject # _____ Date _____

ID # _____ MMRF (8) or S&A (2)

SYSTOLIC (mmHg)/DIASTOLIC (mmHg)

Arm: Left or Right
First Reading _____ / _____ Visit # 1 2 3 4 5

Second Reading _____ / _____ Date _____

Third Reading _____ / _____

Average _____ / _____ (2 closest systolic readings)

Arm: Left or Right
First Reading _____ / _____ Visit # 1 2 3 4 5

Second Reading _____ / _____ Date _____

Third Reading _____ / _____

Average _____ / _____ (2 closest systolic readings)

Arm: Left or Right
First Reading _____ / _____ Visit # 1 2 3 4 5

Second Reading _____ / _____ Date _____

Third Reading _____ / _____

Average _____ / _____ (2 closest systolic readings)

Averages of all 3 averages _____

Comments _____

Morehouse School of Medicine
Department of Family Medicine

MANAGING MULTIPLE RISK FACTORS FOR CARDIOVASCULAR DISEASE

DAMD17-95-C-5067

APPENDIX I

Privacy Agreement

I, _____, agree to not talk about the details of the intervention groups until after I have completed the program. I also agree to not talk about the intervention group experiences during my follow-up evaluations with Ms. Karen Parker or any other project staff member other than the instructor for my group.

_____
Signature

_____
Date

_____
Witnessed by Group Instructor

PATIENT ID #	INITIALS	DATE	VISIT #
_____	_____	__/__/__	_____

NAME: _____

1. Do you expect that the Health Education program will be effective in lowering your blood pressure?

   (a) Not at all (b) A little (c) Somewhat (d) A lot (e) Very much

2. Do you expect the Health Education program will improve your overall physical health?

   (a) Not at all (b) A little (c) Somewhat (d) A lot (e) Very much

3. Do you feel that the Health Education program will improve your mental health and well being?

   (a) Not at all (b) A little (c) Somewhat (d) A lot (e) Very much

(Health Educati

H.E.A.D.-S.M.A.R.T.
Regularity Form

ID# _____

Project _____

Last Name _____ First Name _____

Period Number 1 2 3 4 5 6 7 8 9

10 11 12 13

Period Beginning _____ Period Ending _____

Please write down the type of other homework/ lifestyle modification activity you engaged in (e.g. monitored sodium intake; exercised for 30 minutes). Bring this form with you to your next scheduled meeting.

Date							
Type of lifestyle modification activity (eg. Exercised for 30 minutes; counted fat grams; etc.)							
Type of lifestyle modification activity							
Time you took anti-hypertensive medication (N/A if not applicable)							

INTERVENTION DATA

NAME _____

HOME# _____

WORK# _____

MMRF S&A ID# _____ CYCLE#_____

	Y	N
EXPECTANCY		

SESSION	DATE	ATTENDANCE	COMPLIANCE LIFESTYLE	COMPLIANCE MEDICATION
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
*12				
*13				
TOTALS				

* PLEASE LET SUBJECTS KNOW TO COME 30 MIN. EARLIER DUE TO BLOOD PRESSURES BEING TAKEN AT THESE SESSIONS.

TM Expectancy Form

NAME: _____

1. Do you expect that the Transcendental Meditation program will be effective in lowering your blood pressure?
   (a) Not at all (b) A little (c) Somewhat (d) A lot (e) Very much

2. Do you expect the Transcendental Meditation program will improve your overall physical health?
   (a) Not at all (b) A little (c) Somewhat (d) A lot (e) Very much

3. Do you feel that the Transcendental Meditation program will improve your mental health and well being?
   (a) Not at all (b) A little (c) Somewhat (d) A lot (e) Very much

TM
(Transcendental Meditation)

H.E.A.D.-S.M.A.R.T.
Regularity Form

ID#_____

Last Name_____ First Name_____

Period Number 1 2 3 4 5 6 7 8

Period Beginning_____ Period Ending_____

DATE							
Morning Start/Ending Time							
Evening Start/Ending Time							
Time you took Anti-Hypertensive Medication							

DATE							
Morning Start/Ending Time							
Evening Start/Ending Time							
Time you took Anti-Hypertensive Medication							

Please write the times you begin and end your practice each morning and evening. Bring this form in with you to your next follow-up meeting scheduled for _____ along with any medication prescriptions you are currently taking.

TM INTERVENTION DATA

NAME _____

HOME# _____

WORK# _____

MMRF S&A ID# _____ CYCLE#_____

	Y	N
EXPECTANCY		

SESSION	DATE	ATTENDANCE	COMPLIANCE AM MEDITATION	COMPLIANCE PM MEDITATION	COMPLIANCE MEDICATION
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
*12					
*13					
TOTALS					

* PLEASE LET SUBJECTS KNOW TO COME 30 MIN. EARLIER DUE TO BLOOD PRESSURES BEING TAKEN AT THESE SESSIONS.

Morehouse School of Medicine
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MANAGING MULTIPLE RISK FACTORS FOR CARDIOVASCULAR DISEASE

DAMD17-95-C-5067

APPENDIX J

AFRICAN-AMERICAN STRESS REDUCTION PROJECT

Lifestyle Education Manual Syllabus

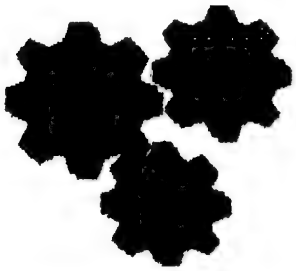
INTRODUCTION

Module 1: Introduction

Objective: Participants will gain understanding, appreciation, and commitment to their health and well being. A rapport will be established between instructor and participants to form a cohesive group.

- Introduction
- Healthy Challenge Quiz
- Nutrition Myths Demystified
- Calcium, Potassium and Magnesium Supplementation
  - Calcium Rich Foods
  - Potassium Rich Foods
  - Magnesium Rich Foods
- Meal Planning

MODULE 2
BODY PHYSIOLOGY



Participants will understand how the human body operates and will make comparisons between normal physiology and hypertensive and heart disease states.

There is an interesting paradox in health and disease prevention. Today we live longer than any other time in history, however some experts suggest that we should go back to living to prehistoric ways.

During this class we will concentrate on the cardiovascular system and what the normal physiology of the heart should look like.

The ancient Greeks believed that the heart was the seat of intelligence; others had thought it was the seat of emotions. Despite its vital importance, the heart is not an organ working in isolation; its part of the cardiovascular system, which includes the blood vessels of the body. All day and all night, tissue cells take in nutrients and oxygen and excretes wastes. Because cells can make such exchanges only with their immediate environment, some means of changing and renewing that environment is necessary to ensure a continual supply of nutrients and to prevent pollution from the buildup of ejected wastes. The cardiovascular system provides the transport system "hardware" that keeps blood in continuous circulation to fulfill this critical homeostatic need.

When stripped of its romantic cloak, the heart is no more than the transport pump, with hollow blood vessels providing the delivery routes. Using blood as the transport medium, the heart continually propels oxygen, nutrients, wastes, and many other substances into the interconnecting blood vessels that move to and past the body cells.

Let's take a look at the heart for a moment (*Show transparency 3-4 "The Cardiovascular System")* (*Point to the right side of the heart)* The right side of the heart collects blood returning to the heart and sends it through the lungs for purification and a fresh supply of oxygen. (*Point to the left side of the heart)* The left side of the heart supplies a new supply of oxygen rich blood to the entire body.

Let's take a closer look at the heart (*Show transparency 3-6 "The Heart")*
This picture shows a more anatomically correct heart. Which arteries do you this collect plaque and cholesterol and cause heart attacks?.....Wrong, it is not the (*Point to the aorta)* large artery called the aorta, but these (*Point to the coronary arteries on the heart)* small arteries on the outside of the heart

called the coronary arteries supplies the hearts own blood supply. These small arteries are smaller than the point of a pencil. It's amazing we all don't have a heart attack!
Actually, the aorta is the largest artery in the body, whose branches ultimately deliver blood to all body organs.

Let's watch this video on just how the cardiovascular system and other human machinery operates.

(Show Video: The Human Body and Cardiovascular System)

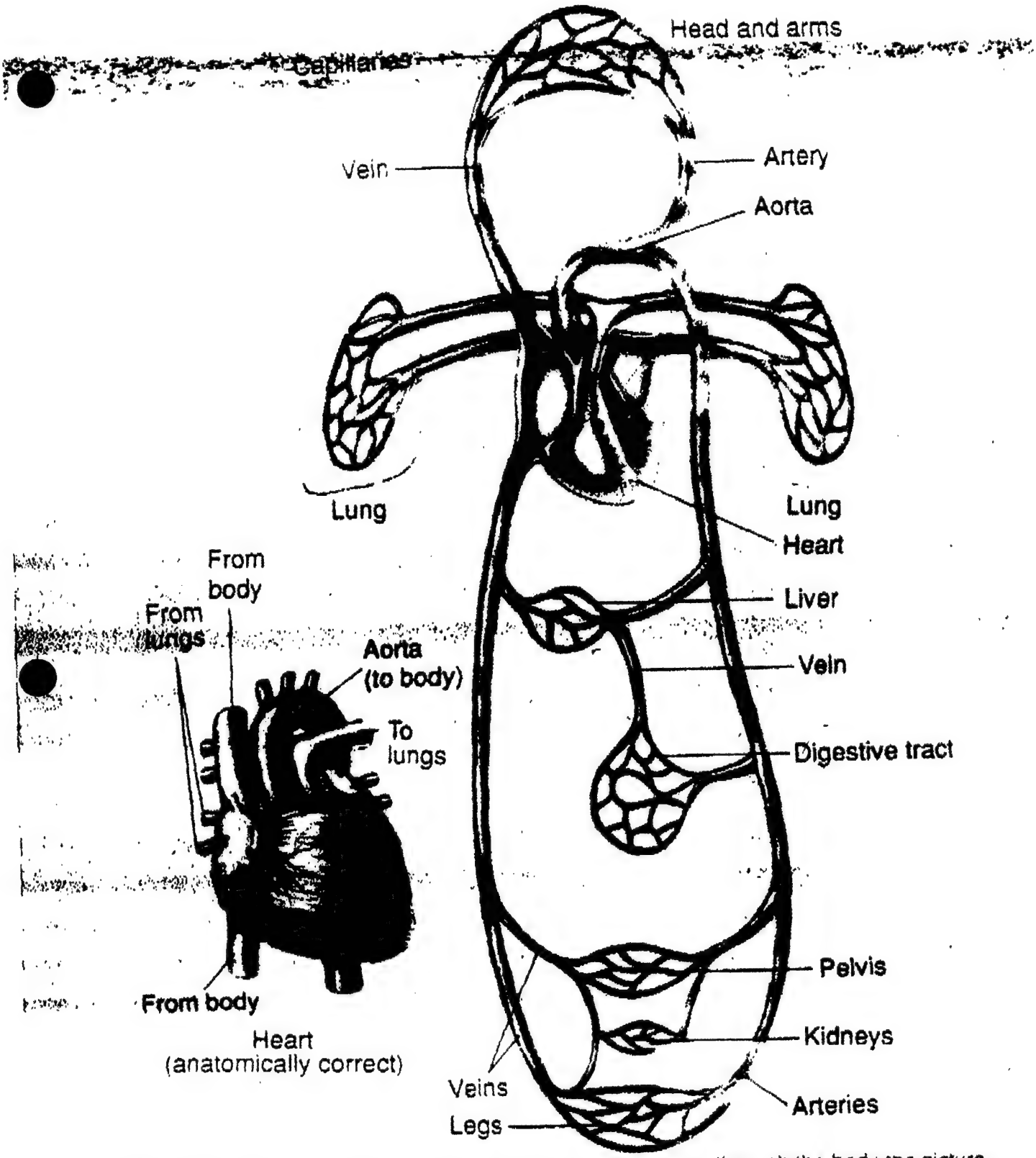
[redacted]

Show participants video of how the human body and cardiovascular system works.

Allow a question and answer session for physiology discussion

[redacted]

-Video of the Human Body and Cardiovascular System @ $12.00 to $150.00
(Contact educational publishers for video list)
-VCR
-Television
-Overhead projector
-Transparency 3-4 "The Cardiovascular System"
-Transparency 3-6 "The Heart"

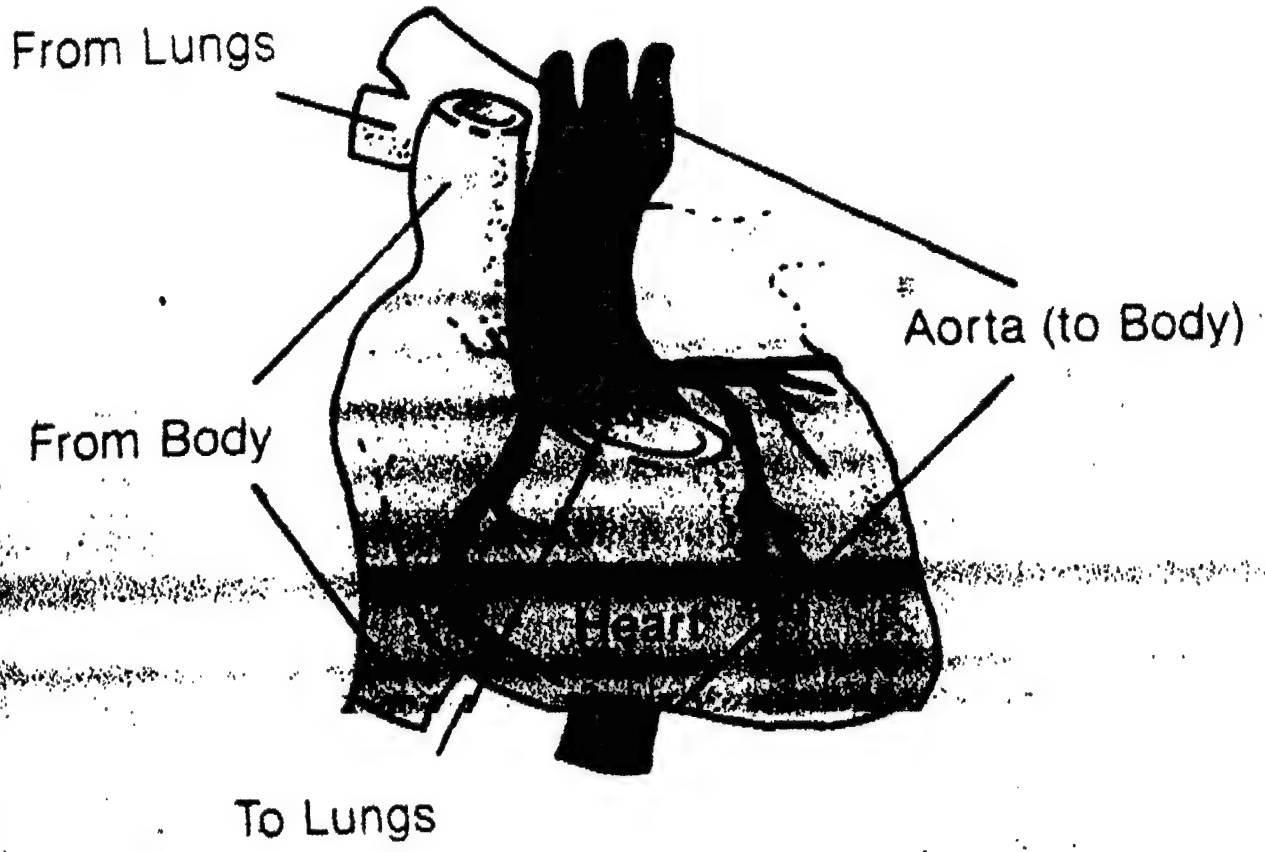


[a]The aorta is the main artery that launches blood on its course through the body the picture is not anatomically correct but is drawn this way for clarity. The aorta actually arises behind the left side of the heart and arcs upwards then divides

Overhead 3-4

The Cardiovascular System

Heart (Anatomically Correct)



Overhead 3-6
The Heart

Module 3: Hypertension and Heart Disease

Objective: The participants will be able to understand the essence of their disease and the lifestyle modifications which are required to lower their blood pressure without medication.

- What's Blood Pressure?
- What's High Blood Pressure?
- What Causes High Blood Pressure?
  - Heredity
  - Race
  - Sex
  - Age
- What Can Be Done About Blood Pressure
  - Diet
  - Exercise and Recreation
  - Medication
- How You Can Help Yourself
- Obesity
- Sodium Sensitivity
- Alcohol Consumption
- Oral Contraceptives
- Physical Inactivity
- Can You Tell When Your Blood Pressure Is High
- How Can High Blood Pressure Hurt Your Body?

CARDIOVASCULAR RISK FACTOR ANALYSIS

Module 4: Cardiovascular Risk Factor Analysis

Objective: Participants will be able to list and prioritize their risk factors for cardiovascular disease.. Participants will write goals for controllable risk factors and lifestyle modifications.

- Just What Is A Heart Attack Or Stroke?
- Cardiovascular Risk Factor Analysis Test
- Self Assessment Test

BODY FAT ASSESSMENT

Module 5: Body Fat Assessment

Objective: Each individual will receive an estimate of percentage of body fat using the skinfold caliper method.

- What Causes Obesity?
  - Genetic Factors
  - Endocrine and Metabolic Factors
  - Dietary Factors
  - Physical Inactivity
  - Socioeconomic and Racial Factors
- Body Fat Assessment Activity

NUTRITION

Module 6: Nutrition

Objective: Participants will have a comprehensive understanding of protein, carbohydrates, and fat. Participants will be able to differentiate between high fat foods and their lower fat counterparts. Each participant will understand how to read a food label.

- On Any Given Day In The United States
- Eating Out The American Way
- Pro's, Carb's And Fat Slide Presentation
- Percent Nutrients In Foods Versus The Human Body
- Glossary
- Lean Life Food Presentation
- Get The Fat Out Of Your Diet
- The New Label Format
  - % Of Daily Values
  - Serving Size

WEIGHT MANAGEMENT

Module 7: Weight Management

Objective: Participants will be able to verbally categorize and write a meal plan for all foods in the American Dietetic Association Exchange List and give the number of servings being shown. Each person will verbally identify personal obstacles in attempted weight loss and write short and long term goals to overcome failures.

- Why Diets Don't Work
- What Happens During Fasting And Overeating?
- What Went Wrong?
- What Can We Do About It?
- Food Guide Pyramid
- Exchange Pattern

EXERCISE & FITNESS

Module 8: Exercise and Fitness

Objective: Given the information on benefits or exercise, each participant will correctly write their own exercise prescription to fit their lifestyle.

- Fitness Facts Quiz
- How Exercise Can Benefit A Long Term Weight Loss Program
- Fitness And Nutrition
    - Fluid and Electrolytes
    - Calories
    - Myths and Facts About Walking and Weight Loss
- Fitness Injury And Prevention
- How To Design Your Fitness Plan

CHOLESTEROL MANAGEMENT

Module 9: Cholesterol Management

Objective: Participants will write dietary and lifestyle modifications to lower their cholesterol by raising their HDL's through exercise and lower the LDL's through a low fat diet. Participants will be able to complete a heart healthy menu using some suggested low saturated fat foods.

- Cholesterol
- HDL Versus LDL
- Saturated Fats
- Polyunsaturated Fats
- Monounsaturated Fats
- Fiber

SODIUM DIETARY MODIFICATIONS

Module 10: Sodium Dietary Modifications

Objective: Participants will write and present low sodium recipe modifications using Herbs and Spices.

- 200 mg Sodium Diet-- No Added Salt
- Ways To Lower Your Salt Intake
- Herbs And Spices
- How Much Salt?

SUBSTANCE ABUSE

Module 11: Substance Abuse

Objective: Participants will seek help if they have any addiction which may detrimental to their health.

- Addiction
- Alcohol
- Vitamin Deficiencies
- Drugs
- Nicotine Addiction
- Caffeine

BEHAVIORAL CHANGE

Module 12: Behavioral Change

Objective: Participants will understand how to replace negative habits with positive new actions. Each person will verbally identify and write personal obstacles in previous weight loss attempts and positive changes to overcome these obstacles.

- Changing Your Dieting Behaviors
- Changing Your Shopping Habits
- Changing Cooking Habits
- Changing Your Eating Behaviors

Module 13: Stress Assessment

Objective: Participants will implement a one-day stress make-over during the next month.

- ✦ Stress Makeover

PRACTICE SESSION

Module 14: Practice Session

Objective: Participants will apply and practice knowledge in nutrition, exercise, and behavior and lifestyle changes.

- Game For Entire Group: Nutriquest Card Game
- Games For Smaller Groups

  Balance: The Game of Living Well
  Health Not So Trivial

EVALUATION

Module 15: Evaluation

Objective: Participants will demonstrate a comprehensive understanding of all areas of lifestyle modification including: Diet, Exercise, and Behavior modification. Participants will take post-test and report on improvements and further modifications. Participants will complete study, feeling like they have made great improvements in their lifestyle.

- Putting It All Together

  Dietary Modifications
  Exercise
  Behavior Modifications

- Post-Test Self-Assessment
- Post-Test Body Fat Percentage

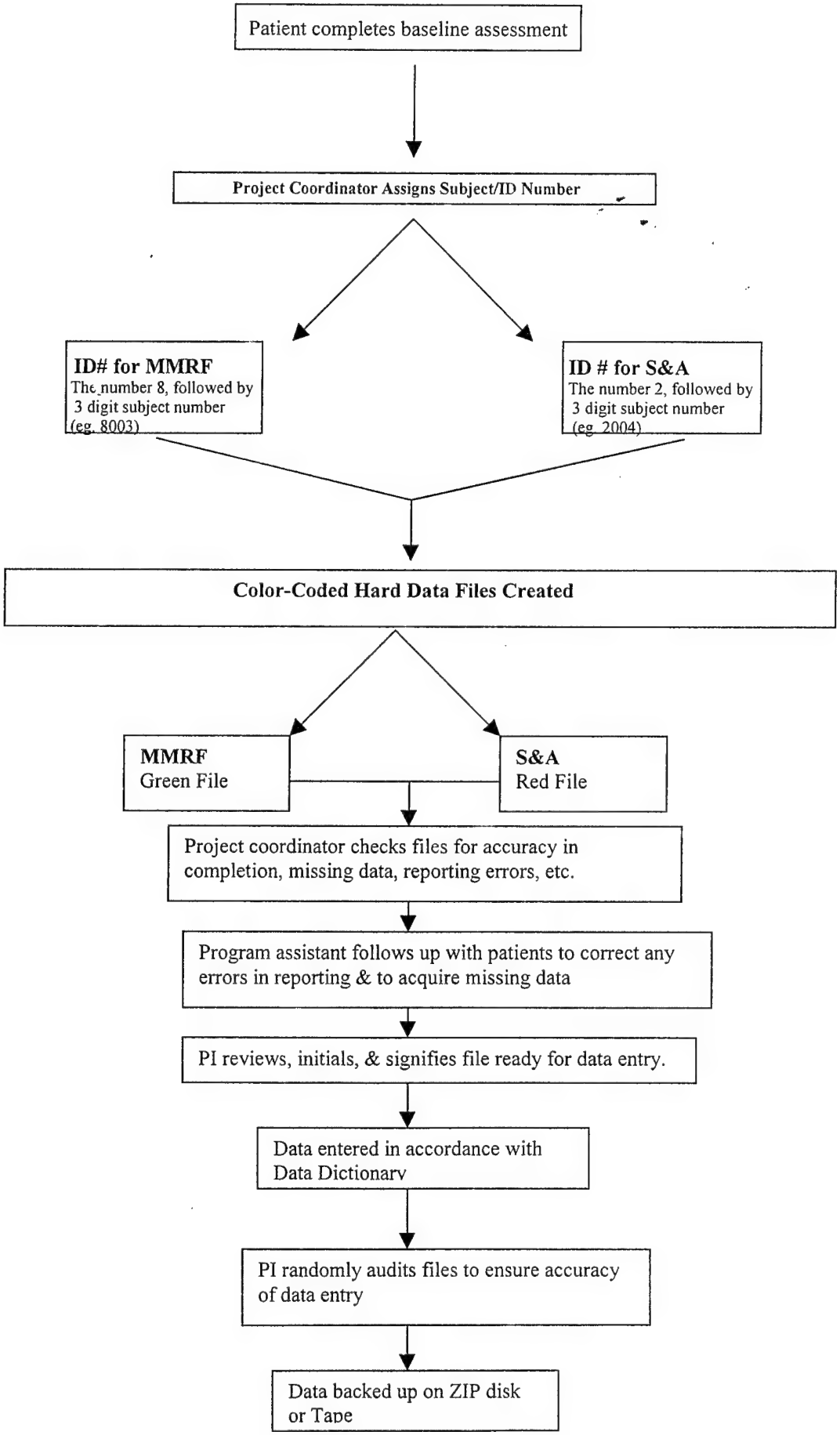
Morehouse School of Medicine
Department of Family Medicine

MANAGING MULTIPLE RISK FACTORS FOR CARDIOVASCULAR DISEASE

DAMD17-95-C-5067

APPENDIX K

DATA MANAGEMENT QUALITY CONTROL



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MANAGING MULTIPLE RISK FACTORS FOR CARDIOVASCULAR DISEASE

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APPENDIX L

BLOOD DRAW / QUALITY CONTROL FOR MMRF

** Participants should fast for 12 hours prior to giving blood

** We will need 4 tubes (A, B, C and D)

** We will be screening for the following: Insulin, Serum Sodium, Potassium, Creatinin, Albumin, HDL, LDL, HDL-C, VLDL, Total HDL, Total Triglyceride, Insulin, Norepinephrine, & Dopamine

Tubes A, B, C and D (10 ml of blood a piece)

↓

Spin **Tube A & B** in serum separated tubes and Separate Serum into Plastic TT

↓

W e Receive **Tubes A & B** (Serum only) For Quality Control **[AML keep tubes C & D]**

↓

Tubes A & B Labeled and Stored at –80 Degree Celsius for 1 month afterwards quality controlled assays are performed

Analyze **Tube A** [and TT **C** from AML] for Insulin, Serum Sodium, Potassium, Creatinin, Albumin, HDL, LDL, HDL-C, VLDL, Total HDL, Total Triglyceride and Insulin (**Testing for these substances require the use of the RED top TT).** Analyze **Tube B** [and TT **D** from AML] for Norepinephrine and Dopamine **(Testing for these substances require the use of the GREEN top TT).**

Transfer of serum must be done using the aseptic technique. Samples must be maintained under optimum conditions to prevent contamination and degradation. For example, keep samples cold when possible and always use sterile containers.

For questions please contact Karen Parker (404) 756-1435 or Celedor Hutto (404) 756-5734.

Morehouse School of Medicine
Department of Family Medicine

MANAGING MULTIPLE RISK FACTORS FOR CARDIOVASCULAR DISEASE

DAMD17-95-C-5067

APPENDIX M

Medical Backup Procedures

The medical back-up physician for the project, Dr. George Rust should be contacted immediately @ 404-756-1236 or by pager @ 404-871-8946 for consultation/evaluation in the event patients report any of the following:

1) Patient reports any of the following symptoms of heart attack:
   - dizziness
   - palpitations
   - uncomfortable pressure, squeezing or pain in the center of the chest lasting more than two minutes
   - pain spreading to the shoulders, neck or arms
   - sweating, nausea, shortness of breath and weakness

2) Patient reports any of the following symptoms of stroke:
   - sudden weakness or numbness of the face, arm or leg on one side of the body
   - sudden dimness or loss of vision, particularly in one eye
   - loss of speech, or trouble talking or understanding speech
   - sudden, severe headaches with no apparent cause
   - unexplained dizziness, unsteadiness or sudden falls, especially along with any of the previous symptoms

3) Patient reports any of the following symptoms of malignant hypertension:
   - morning headaches
   - blurred vision
   - dyspnea
   - symptoms of uremia
   - diastolic blood pressure >110

4) Patient's blood pressure exceeds 179/110 mmHg.

Patients whose blood pressure is elevated to 140/90 or above should be referred to their physician for medical evaluation or follow-up. Dr. Rust should be contacted if patient reports other symptoms of medical distress that are not listed. In the event Dr. Rust is not available, medical consultant, Dr. Harry Strothers should be contacted at (404) 756-1239 or medical resident, Dr. Linda McKinnon (404) 278-8182 (Pgr). Alternatively, you may refer patients to the Family Practice Center @ 505 Fairburn Rd., 404-756-1200 or to a Morehouse Medical Associates physician @ 75 Piedmont Ave. In medical emergencies, you should dial 911 immediately. If patient respiration and cardiac function ceases, you should dial 911 then initiate cardiac pulmonary resuscitation.

In the event a medical emergency occurs, Dr. Charlie Lollis should also be contacted immediately @ (404) 756-5753 (office); (404) 212-7831 (residence); or (770) 707-6291 (pager).

Medical Backup Directory of Physician Consultants

1. Dr. George Rust	Office:	(404) 756-1236
	Pager:	(404) 871-8946
2. Dr. James Everett	Office:	(404) 756-1232
	Pager:	(404) 871-8854
3. Dr. Harry Strothers	Office:	(404) 756-1239
4. Dr. Linda McKinnon (Resident)	Home:	(770) 323-7339
	Pager:	(404) 278-8182

Morehouse School of Medicine
Department of Family Medicine

MANAGING MULTIPLE RISK FACTORS FOR CARDIOVASCULAR DISEASE

DAMD17-95-C-5067

GRANT/
CHANGES IN METHODOLOGY & DESIGN

Change in Methodology	Principal Investigator	Date of Change
reduction in sample size from 200 civilian and 200 military to 120 of each population	E.H. Johnson	June, 1995
reduction of follow-up periods to 1 & 6 mos.	E.H. Johnson	June, 1995
change selection criteria so that being overweight no longer inclusionary criteria	E.H. Johnson under reccomendation of technical representative, Dr. Sam Shannon	June, 1995
reduction in sample size from 120 military/civilian to 100 of civilian population	C.M. Lollis with approval of technical representative, Dr. Sam Shannon	November, 1997
change selection criteria from mild hypertension to high-normal to mild hypertension (130-159/85-104 mmHg)	C.M. Lollis under reccomendation of technical representative, Dr. Sam Shannon	November, 1997
operationalizaiton of "other risk factors ..." to at least 2 additional risk factors besides high normal/mild htn (i.e. overweight, family history of CVD, drinking, smoking, sedentary lifestyle, high cholesterol)	C.M. Lollis under reccomendation of technical representative, Dr. Sam Shannon	November, 1997
change in selection criteria from ages 18-30 to ages 18-70	C.M. Lollis with approval of technical representative, Dr. Sam Shannon	November, 1997
change in selection criteria to include individuals using antihypertensive medications in addition to those who are not taking medication	C.M. Lollis with approval of technical representative, Dr. Sam Shannon	November, 1997
change from laboratory studies to be conducted within the 1st 15 days of menstrual cycle to no inclusion for time lab studies are conducted	C.M. Lollis with approval of technical representative, Dr. Sam Shannon	November, 1997
Exclusion of fasting glucose > 140 changed to exclusion of fasting glucose >120	C.M. Lollis under reccomendation of technical representative, Dr. Sam Shannon	November, 1997
Health education group modeled after TM/AMT group changed to group modeled after TM group with respect to equating for time and attention, but not 5 consecutive day format	C.M. Lollis with approval of technical representative, Dr. Sam Shannon	November, 1997
AMT/TM combined group revised so as to drop AMT as part of the intervention	C.M. Lollis with approval of Dr. John Stuart, technical representative	October, 1998
Subject payment reduced from $200 to $160	C.M. Lollis with approval of technical representative, Dr. Sam Shannon	November, 1997

Managing Multiple Risk Factors For Cardiovascular Disease
DAMD17-94-BAA
Addendum: Changes in Methodology/Design

I. ABSTRACT

Current research provides evidence that a higher prevalence of obesity, a more centralized fat pattern and a clustering of cardiovascular risk factors (i.e. overweight/obesity, hypertension, hyperinsulinemia, insulin resistance, dyslipidemia, neurohumoral activation and anger/hostility) contribute to the racial differences in cardiovascular risk and events among women. High levels of socioeconomic stress, higher dietary fat intake and sedentary lifestyle are more prevalent among black than white women. The proposed study will address the issue of whether the cluster of risk factors for cardiovascular disease among black women can be better controlled through the use of a stress reduction intervention that reduces the sympathetic nervous system arousal that is related to elevations in risk factors. This is a randomized, single-blind, controlled study of the efficacy of meditation combined with anger management versus a health education program for reducing cardiovascular risk factors in 100 black civilian women and 100 military women. All participants will have high normal 130/80 or mild hypertension and at least two additional risk factors fro cardiovascular risk factor cluster, health factors, psychosocial/quality of life factors, interpersonal and family stress, job stress and job performance.

Statement of Work

This is a randomizedl, single blind study of the effects of a stress-reduction program consisting of anger management therapy and mediation on hypertension and other risk factors for cardiovascular disease (e.g. high cholesterol, triglycerides, plasma catecholamines, overweight/obesity, smoking, drinking, etc.) in 100 military and 100 civilian women. All participants will have high-normal hypertension (130/80 mmHG) and at least two other risk factors for cardiovascular disease such as elevated cholesterol or insulin, overwight/obesity, genetic heritability, smoking, drinking, etc. All women will have follow-up exams after 1 and 6 months to assess the impact of the intervention on cardiovascular risk factor cluster, heatlh factors, psychological factors, interpersonal and family stress, job stress and job performance. The proposed research will be conducted across three years and the plans for the work are outlined below.

Year 1:

*Recruit 40 civilian women with multiple risk factors for cardiovascular disease into the study.
*Baseline psychophysiological and psychosocial assessments of 40 women prior to randomization. Group sizes will be restricted to 10-15 members per intervention group each cycle and the duration of interventions is to last 12 weeks. We anticipate it taking 2 cycles to complete the interventions for 60 women with the cumulative time for 60 women to complete the intervention being 6-months. We anticipate intervention groups will start within 1 month of patients' baseline assessments.
*Complete cycles 1 and 2 of the intervention (N=60 women).
*Complete 1 month post-treatment assessment for 30 civilian women.

Year 2

*Complete 1 month post-treatment assessment for 30 civilian women
*Complete 6 month follow-up for participants (N=60) from cycles 1,2.
*Recruit 100 women (40 civilian/60 military women) into the study.

*Initiate recruitment of military women.
*Baseline psychophysiological and psychosocial assessments of 100 women prior to randomization.
*Complete 4 intervention cycles (cycles 3-6) for 100 participants.
*Complete 6-month follow-up for participants (N=50) from cycles 3,4.
*Complete 1-month post-treatment assessment for 75 women.
Year 3:
*Complete 1-month post-treatment assessment for 25 women.
*Complete 6-month follow-up for participants (N=50) from cycles 5,6.
*Recruit 40 military women into study.
*Baseline psycholphysiological and psychosocial assessments of 40 women prior to randomization.
*Complete 2 intervention cycles (cylcles 7,8) for 40 participants.
*Complete 6-month follow-up for participants (N=50) from cycles 5,6.
*Complete 1 and 6-month follow-up for participants (N=40) from cycles 7,8.

Title of Study: *(120 Characters Maximum)* Managing Multiple Risk Factors For Cardiovascular Disease Through Anger/Hostility Control and Meditation

Keywords: *(6-8 words)* overweight, hypertension, multiple risk factors, stress management, anger/hostility, meditation, clinical intervention

Abstract: *(Type within outline; approximately 200 words)*

Current research provides evidence that a higher prevalence of obesity, a more centralized fat pattern, and clustering of cardiovascular risk factors (i.e., overweight/obesity, hypertension, hyperinsulinemia, insulin resistance, dyslipidemia, neurohumoral activation and anger/hostility) contribute to the racial differences in cardiovascular risk and events among women. High levels of socieconomic stress, higher dietary fat intake and sedentary lifestyle are more prevalent among black than white women. Although weight loss is an effective means for reversing the risk factor cluster, the magnitude and duration of weight loss are often quite limited, especially among black women. Consequently, new approaches are required for addressing the health risk associated with overweight/obesity for black women. The proposed study will address the issue of whether the cluster of risk factors for cardiovascular disease among black women can be better controlled through the use of a stress reduction intervention that reduces the sympathetic nervous system arousal that is related to elevations in the risk factors. This is a randomized, single-blind, controlled study of anger/hostility management combined with meditation versus an intensive educational program among 200 black civilian women and 200 military women. All participants will have mild-hypertension and be >10% above weight and have other risk factors for cardiovascular disease. Post-treatment follow-up exams will be conducted at 1, 6 and 12 months to assess the impact of the intervention on cardiovascular risk factor cluster, health factors, psychological factors, interpersonal and family stress, job stress and job performance.

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Statement of Work.

This is a randomized, single-blind, controlled study of anger/hostility management combined with meditation verses a intensive educational program alone among 200 Black civilian women and 200 military women. All participants will have mild-hypertension and be >10% above ideal weight and have other risk factors for cardiovascular disease such as elevated cholesterol or insulin. All women will have follow-up exams after 1, 6 and 12 months to assess the impact of the intervention on cardiovascular risk factor cluster, health factors, psychological factors, interpersonal and family stress, job stress and job performance. The proposed research will be conducted across four years and the plans for the work are outlined below.

Year No. 1

*100-125 civilian women with multiple risk factors recruited for the intervention.
*Baseline physiological and psychological assessments of 100-125 women prior to randomization to interventions.
*Intervention groups started mid-way through the years. Group size restricted to 20-25 participants per cycle and the duration of the group interventions will be 8 weeks. Therefore, it will take 5 cycles (10 months) to complete the interventions for 100-125 participants.
*Complete the 1 month post-treatment assessment for 100-125 civilian women .

Year No. 2

*Complete the 6 month post-treatment assessment for civilian women who complete intervention during year 1.
*Baseline physiological and psychological assessments of 100-125 civilian women prior to randomization to interventions.
*Continuation of intervention groups for the 100-125 participants instructed in the 5th and 6th cycle. This will take 4-5 months.
*Follow-up assessment after 1 and 6 months of the intervention for civilian women who started the intervention during year 2.
*Annual mail follow-up stress, health and behavior questions to all civilian women who completed the initial screening during year 1.
*Follow-up assessment after 12 months of the intervention for civilian women who started the intervention during year 1.
*Initiate work with military women.
*25 military women with multiple risk factors recruited for the intervention and baseline physiological and psychological assessments conducted prior to randomization to intervention groups.

Year No. 3

*100 military women ages 18-30 with multiple risk factors for cardiovascular disease recruited for the intervention. Baseline physiological and psychological testing conducted prior to the in the intervention. It will take 10 months to complete the intervention for 100 women (5 cycles of 20 women per group for a 8 week intervention cycle.)
*Follow-up assessment after 1 and 6 month of intervention for military women who completed intervention in year 2 and those who received it at the start of year 3.
*Follow-up assessment after 12 month of intervention for civilian women from year 2.
*Annual mail follow-up stress, health and behavior questionnaires to all civilian women who completed the initial screening. The women will receive questionnaires concerning the occurrence of stress, emotional reactivity to these stressors, and anger/hostility and stress coping styles. Questions concerning job performance, work relationships, and family stress will be assessed. Information about changes in health and health behaviors will also be assessed at these times.

Year No. 4

*75 military women with multiple risk factors recruited for the intervention and baseline physiological and psychological assessments conducted prior to randomization to intervention groups.
*Follow-up assessments of military women after 1 and 6 months.
*Follow-up assessment after 12 month of intervention for military women enrolled during year 3.
*Annual mail follow-up stress, health and behavior questionnaires to all civilian and military women who completed the initial screening one year ago.
*Data analyses to address aims and hypotheses. Preparation of papers for publication.
*Final report to summarize the results of the study prepared during the last 4 months of the year.

BODY OF PROPOSAL

Project Overview: The mortality rate for cardiovascular events is greater in African American than in white women and most epidemiologists contend that targeting only high risk groups, such as the hypertensive population, has little impact on population attributable risk. However, in black women, 42% of the population attributable risk for premature mortality is present in hypertensive patients compared to 17% in white women. This racial difference in population attributable risk of hypertension reflects a higher prevalence and a greater adverse effect of elevated BP in black women. These findings justify a high risk strategy as one approach for reducing the excess cardiovascular morbidity and mortality among black women. The latest research provides evidence suggesting that a higher prevalence of obesity, a more centralized fat pattern, and clustering of cardiovascular risk factors contribute to the racial differences in cardiovascular risk and events among women. Although weight loss is an effective means for reversing the risk factor cluster, the magnitude and duration of weight loss are often quite limited, especially among black women.

The risk factor cluster includes overweight/obesity, hypertension, hyperinsulinemia, insulin resistance, dyslipidemia, neurohumoral activation and anger/hostility. High levels of socieconomic stress, higher dietary fat intake and sedentary lifestyle are all more prevalent among black than white women. These socieconomic, educational and lifestyle stresses appear to converge and result in increased sympathetic drive and augmented neurovascular tone. The heightened sympathetic drive as well as the increased vascular reactivity emerge as major contributors to the risk factor cluster in black women.

Previous research suggests that behavioral interventions directed at stress reduction are effective in lowering BP. Other research shows evidence that anger/hostility and exaggerated reactivity to stress is a significant independent correlate of hypertension, especially in blacks. Finally, a number of studies have shown that Meditation is more effective than other stress reduction methods in lowering BP. Post-hoc analyses of one such study (Schneider et al., 1992) indicate that one form of meditation, Transcendental Meditation (TM), is effective in black women, and that TM is more effective than other stress reduction approaches in obese African Americans. Reduction of BP in hypertensive patients is an important objective, since pressure-related complications such as stroke, heart failure, and renal insufficiency and failure are significantly reduced and/or delayed. However, cardiovascular risk factors often cluster which may explain why lowering BP alone does not achieve the expected risk reduction in atherosclerotic events including coronary heart disease.

Since meditation appears to reduce the stress and the associated increase in sympathetic nervous system activation which contribute to the risk factor cluster, meditation may be effective not only in reducing BP, but other components of the risk factor cluster and angry/hostile responses to stress. To our knowledge, the effects of meditation on the risk factor cluster have not been examined. Two hundred civilian and 200 military, African-American women will have baseline assessments of cardiovascular disease risk factors (hypertension, hyperinsulinemia, body fat distribution, dietary sodium and potassium intake, dyslipidemia, neurohummoral activation) and psychosocial (anger/ hostility, anxiety, depression,

family/job stress, stress coping styles, smoking, drinking) risk factors. Women with mild hypertension and who are >10% overweight and who have other risk factors for cardiovascular disease will be enrolled in the intervention. All laboratory studies will be conducted with women while they are within the first 15 days of their menstrual cycle. Anger/hostility management combined with stress reduction through the practice of meditation will be compared to an intensive education program which includes instructions on regulation of the risk factor cluster. This intervention study will determine if the combination of meditation and anger/hostility management reduces the psychological and physiological responses associated with stress induced in a laboratory setting and real-stress associated with civilian and military life. If the combination of meditation and anger/hostility management proves effective for controlling the risk factor cluster, managing stress, and improving job/personal performances in black women, then this would comprise a comparatively low-cost intervention which could be implemented on a larger scale with women from other ethnic groups.

HYPOTHESIS AND SPECIFIC AIMS FOR BASELINE MEASURES: Determine the interrelationship between anger/hostility and both cardiovascular and psychological risk factors for civilian and military women.

Hypothesis #1: Anger/Hostility will be positively associated with higher blood pressure, lipids, sympathetic activation (as reflected by plasma norepinephrine), and body fat.

Hypothesis #2: Anger/Hostility will be positively associated with negative health practices such as smoking, drinking and non-adherence to suggested physical conditioning guidelines.

Hypothesis 3#: Anger/Hostility will be positively associated with greater levels of family and job stress, anxiety and depression.

Hypothesis #4: Anger/Hostility will be negatively associated with job performance, productivity at work, relationships with co-workers and supervisors.

HYPOTHESIS AND SPECIFIC AIMS FOR THE INTERVENTION: Determined if the combination of anger/hostility management and meditation lowers the composite score for risk factor clusters, reactivity to stress, and improves family/job stress and work performance more effectively than lifestyle change alone for civilian and military women with multiple risk factors for cardiovascular disease.

Hypothesis #1: Anger/hostility management in combination with meditation will reduce the risk factor cluster more effectively than lifestyle changes alone by lowering sympathetic drive and vascular reactivity.

Hypothesis #2: Anger/hostility management in combination with meditation will reduce psychological stress (i.e., anxiety, anger, depression), lipids and physiological responses associated with laboratory induced stress and real stress associated with civilian and military life as reflected by 24-hour blood pressure and behavioral assessments.

Hypothesis #3: Civilian and military women who receive training in anger/hostility management + meditation will have better relationships with co-workers and supervisors, perform more efficiently and

effectively on their jobs, and experience less stress during the follow-up phase. It is also predicted that the anger/hostility management + meditation intervention will enhance the adaptability of military women during deployments, training, and while experiencing traumatic and post-traumatic incidents.

MILITARY SIGNIFICANCE

*The immediate usefulness of this study is to provide a non-drug alternative for preventing and managing psychological stress and cardiovascular disease risk factors for black women who are at high risk for cardiovascular disease and the experience of anger/hostility related to stress. The determination of whether a non-drug treatment can be successfully used to treat this condition is important because traditional drug therapy has some side effects that cause drowsiness and can interfere with performance, particularly during time of stress. Furthermore, some of the antihypertensive medications disrupt the homeostasis of the cooling system of the body and require individuals to consume large amounts of water that may not be available in certain environments. While there is evidence that cardiovascular disease risk factors are somewhat lower for military than civilian women (Bielenda et al., 1993), there is evidence that the incidence of cardiovascular disease risk factors are higher among blacks in the military compared to whites (Gorham et al., 1993).

*The long-term usefulness of this study can be measured by the lower rates of stress-related problems and cardiovascular disease that are predicted for black women who receive the training in anger/hostility management and meditation. It is also predicted that these women will cope better with stress associated with military life. The amount of contact with health care providers and dollars used to address medical and psychological problems will be substantially reduced for women who receive this intervention. Since people who regularly meditate are more well-adjusted to handle stress, women who receive the intervention are also expected to make better decisions and perform more efficiently and effectively during times of stress, adjust better to periods of sleep deprivation, have better relationships with co-workers and supervisors, and have a higher job performance, and increased productivity. These issues can be addressed through follow-up studies of the military and civilian women who completed the intervention. Through long-term follow-up it will also be possible to determine whether women who received the anger/hostility + meditation intervention adjust better to deployment, training, traumatic and post-traumatic incidents than control group participants.

*The implementation of an anger/hostility + meditation training program is very cost effective and can be implemented as part of basic training and officer training programs. If the program is widely used, there could be a dramatic increase in the performance of recruits and reductions in the immediate and long-term post-traumatic adjustment problems that are associated with traumatic experiences such as what is recently reported for Operation Desert Storm (Sutker et al., 1994; Marcum and Cline, 1993; Engle et al., 1993; Southwick et al., 1993) and the relatively brief situation at the Persian Gulf War (Perconte et al., 1993). One such study using meditation in the treatment of post-Vietnam adjustments does exist and the results were favorable (Brooks and Scarano, 1985).

*In the event that it is not possible to recruit military women for the study during years 3 and 4 we will recruit another group of 200 civilian women who are all within the last 7 days of their menstrual cycle. This way it will be possible to determine whether phases of the menstrual cycle effects reactivity to stress and performance among black women.

BACKGROUND AND SIGNIFICANCE

Estimates suggest that 30-40% of the excess mortality noted among black Americans can be attributable to heart disease and stroke and one of the strongest contributors to this disproportionately high rate of cardiovascular disease among African-Americans is essential hypertension which is on average 200% that of the majority population. As a consequence, mortality rates for hypertensive disease (Gillum, 1979; Secretaries Task Force an Black and Minority Health, 1986; HDFGP, 1977) are reported to be five times higher in black men age 55 to 59 compared to white men and 7.5 times higher in black women age 55 to 59 compared to white women. Not only is there greater prevalence of these conditions, but there are increased incidence, severity, target organ damage and lower treatment effectiveness rates (Saunders 1991). At present the extent to which these differences are due to variations in genetic susceptibility, familial factors, or the influence of environmental stresses, is not clearly elucidated (Grim et al., 1984; Canessa et al., 1984, 1990). Nevertheless, there is ample evidence indicating that the precursors to cardiovascular disease emerge earlier in life for blacks (Saunder 199; Anderson, 1989).

Whereas the cause of essential hypertension is unknown, it is generally agreed that there are multiple pathophysiological mechanisms involved (Kaplan 1990; Canessa et al., 1984, 1990; Weder et al., 1984; Johnson et al., 1992). A host of factors, including obesity, insufficient potassium and calcium intake, and high levels of anger/hostility may contribute to the higher prevalence of hypertension among African American (Anderson et al., 1989). Recent research suggests that repeated exposure to physical and psychological stresses results in autonomic nervous system arousal and cardiovascular hyperreactivity in certain individuals (Pickering and Gerin, 1992; Falkner et al., 1989; Tischenkel et al., 1989; Anderson et al., 1989; Light et al., 1989; Anderson, 1989). Moreover, the combined effect of these processes is thought to lead to vascular autonomic difficulties, hormonal malfunctions, and hypertension (Mathews et al., 1985; Krantz and Manuck, 1984; Esler et al., 1977).

Why Focus On Overweight and Obese African American Women?

Black women are not only twice as likely than white women to be obese, but they also tend to have the higher risk abdominal fat distribution (Kumanyika, 1987; Gillum, 1987). Twenty-four hour urine norepinephrine excretion is greater in subjects with upper body obesity compared to age-matched individuals over a wide age range (Troisi et al., 1991). Plasma norepinephrine levels are higher in obese than in lean volunteers and decline with weight loss. (Sowers et al., 1982). Obese hypertensive women have higher insulin levels and are more resistant to insulin-medicated glucose disposal than obese normotensive women (Stern and Haffner, 1986). As expected, black women have a 30-100% greater

prevalence of diseases associated with abdominal obesity (Lackland et al., 1992) and insulin resistance including hypertension, diabetics, and related cardiovascular complications such as coronary heart disease, stroke, and congestive heart failure (Peiris et al., 1989; Stern and Haffner, 1986). The reasons for the excess obesity in black women are not fully understood but may include lower socioeconomic status and associated stress (Myers, 1991), a higher prevalence of sedentary lifestyle (Washburn et al., 1992; Ravussin et al., 1988), and consumption of more dietary fat (Lackland and Wheeler, 1990). Not only is weight loss very difficult to maintain over the long-term in the general population but black women appear less successful than white women at losing weight in controlled multicenter studies (Kumanyika et al., 1991).

Black women are the most sedentary demographic subset (Washburn et al., 1992). Aerobic exercise reduces sympathetic and augments parasympathetic tone. Physical activity is inversely related to BP independently of adiposity (National High Blood Pressure Education Program, 1992). The risk of sedentary life extends across age, gender, and racial lines and many increase risk for coronary heart disease (CHD). Thus, a sedentary lifestyle, which is common among black women, probably contributes to sympathetic activation which leads, in turn, to the elevation risk factors such as lipids and insulin.

Black women in one study reported significantly more frequent consumption of foods high in total and saturated fat than white women (Lackland and Wheeler, 1990). A high as compared to low fat diet raises heart rate, 24-hour mean BP, and pressor reactivity to norepinephrine, which is meditated primarily by vasoconstriction. Diets high in fat, particularly saturated fat, also contribute to dyslipidemias and elevated insulin (Grundy, 1986). Finally, some possible interrelations of psychosocial factors and obesity in contributing to hypertension among blacks have been explored (Johnson, 1990; Smyth, 1990; Kumanyika and Adams-Campbell, 1992) and the findings suggest that the manner that anger/hostility is managed is important.

Overall, these findings suggest that new approaches are required for addressing the health risk associated with overweight/obesity for black women. The proposed study will address the issue of whether the cluster of risk factors for cardiovascular disease among black women can be better controlled through the use of a stress reduction intervention that reduces the sympathetic nervous system arousal that is related to elevations in the risk factors.

Stress, Anger/Hostility, and Hypertension Among Black Americans

There is sufficient evidence to suggest that blacks in the United States encounter stressful socioeconomic situations and environmental situations that elicit high levels of anger and hostility (Johnson and Broman, 1987; Broman and Johnson, 1988; Harburg et al, 1973; Diamond, 1982). In the U.S., lower socioeconomic status whether defined by income, education, or occupation is strongly related to greater cardiovascular mortality, morbidity and hypertension (James, 1985). It has been proposed that the severe environmental and psychosocial stress to which blacks are subjected (lower socioeconomic, higher rates of poverty, higher unemployment, lower status of occupation, exposure to racism and more

crowded stressful living environments) leads to chronic autonomic arousal, which over time contributes to hypertension (James, 1985; Meyers et al., 1989). Support for this was provided by the Detroit Blood Pressure Project (Harburg et al., 1979) which showed that blacks in high social stress areas of the city had greater pressures than black residing in low stress areas. Johnson (1987), Johnson and Broman (1987) and Broman and Johnson (1988) also reported that the prevalence of hypertension and other major health problems for blacks in the National Survey of Black Americans was higher for participants who were unemployed, previously married, and poor (incomes less then $5,000/year, and not well educated--less than 12 years of school). Similarly, James and Kleinbaum (1976) reported that blacks residing in high stress counties in North Carolina were twice as likely to die from hypertension-related diseases than blacks in low stress countries.

Other research has converged on the possibility that anger conflict is related to a greater negative and stressful life events among African-American (Johnson and Broman 1987; Broman and Johnson 1988; Siegel, 1984; Johnson and Greene, 1991), and that black people who have difficulties in handling their anger behave in ways that enhance hostile reactions with others and generate more psychological distress for themselves (Johnson and Broman, 1987; Broman and Johnson, 1988). These persons through negative and combative interpersonal behaviors (Van Egeren et al., 1982; Suls et al., 1979) may cause many unpleasant life events (e.g., job loss, divorce or marital difficulties, loss of friends and other avenues of social and emotional support) as well as engage in several negative health behaviors such as excessive cigarette smoking and drinking, over-eating, or ignoring early symptoms of fatigue and of ill health (Novaco, 1975, 1991,1992; Johnson, 1992; Williams et al., 1985; Rosenman, 1985).

In other findings with the National Survey of Black Americans (Broman and Johnson, 1988), we also discovered that conflict about the management of anger is an important predictor of life stress among black adults, and that black people with high levels of anger conflict are more likely to experience negative life events such as problems with money, job, family or marriage, criminal victimization problems, problems with people outside of the family, children, police officers, love-life and even racism. The overall impression of these data suggest that anger may be a risk factor for health problems via its association with negative life events for blacks.

Anger/Hostility and Hypertension

A large number of studies have reported a relationship between hypertension, anger, hostility, and aggression (for reviews see Diamond, 1982; Johnson and Julius, 1990). The Detroit Study, which was conducted in the 1970's was to examined the relationship between anger-coping styles and chronic socio-ecological stress in a sample of 1,000 residents of the city of Detroit (Harburg et al., 1973; Harburg et al., 1979; Gentry et al., 1982; Gentry, 1985). The results indicated that an Anger-In coping response is associated with higher diastolic blood pressure for both males and females. The relationship between anger-coping style and hypertension was essentially the same for all the gender and race groups. Results from other analyses of these data (Gentry et al., 1982; Gentry, 1985) show the odds of having hypertension were higher for blacks, males, persons with high suppressed anger (Anger-In) scores and

residents of high-stress areas. Most importantly, an individual's odds of having hypertension increased if he or she had more than one of the three risk factors. Of the individuals with no risk factors, 9 percent had hypertension, compared to a 33-percent hypertension rate for individuals with three risk factors.

In another study, a relatively strong relationship between hypertension and suppressed hostility (Anger-In) was revealed using adolescents as subject (Johnson et al., 1987a, 1987b; Johnson, 1989, 1990). Although a number of personality and traditional risk factors significantly predicted elevated blood pressure for both blacks and whites as well as for males and females, suppressed anger (Anger-In) turned out to be the most important predictor of elevated blood pressure. Further analysis of these data revealed that the management of anger was one of the characteristics of overweight subjects (Johnson, 1990).

Participants from the Michigan Statewide Blood Pressure Study were representative of the adult population of the state (Cottington et al., 1985). Of the 3,073 adults, age 18-96 years, a subsample of 444 subjects (35% blacks) completed a special survey designed to assess more comprehensively a variety of psychosocial factors, including anger. Among both men and women, those who generally did not express their anger and who tended to harbor grudges, hostility, and aggressive impulses had higher diastolic blood pressure. Among women, those who rated their relationship with family members and best friends more poorly had higher blood pressure.

Several studies have determined whether individuals with high levels of anger/hostility and job stresses that chronically provoke anger are at greater risk of hypertension than persons who are under less stress (Cottington, 1983; Cottington et al., 1986; Mathews et al., 1987). The results show that hypertension is related to job stress among those who chronically experienced but suppressed their anger/hostility. The relationships between hypertension and both "job-future ambiguity" and "dissatisfaction with co-workers and promotions" were consistently modified by suppressed anger/hostility and were independent of known risk factors for hypertension (e.g., age, weight, smoking, alcohol consumption, family history of hypertension).

In other studies (DeQuattro et al., 1981; Sullivan et al., 1981) hypertensive patients and individuals with normal blood pressure were compared on the psychological measures and their blood pressure, heart rate, and plasma norepinephrine and epinephrine responses to isometric handgrip exercise and a mental challenge stress task consisting of a serial subtraction problem. Hypertensive patients had higher levels of suppressed anger and scored higher on the anxiety and depression measures than the normal control subjects. Similar findings were reported in another study (Perini et al., 1986).

Anger, Stress, and Elevated Cholesterol

Elevated levels of total and low levels of high-density lipoprotein (HDL) cholesterol have been clearly recognized as one the important risk factors for coronary heart disease (CHD) in black and white Americans (Gillum, 1984; Gillum and Grant, 1984; Grundy and Winston, 1989; Becker, 1989; Kowalski, 1989; King, 1989). The extent of coronary atherosclerosis and CHD has been found to be positively related to total cholesterol (Kannel, Castelli and Gordon, 1979), low-density lipoprotein cholesterol (LDL; Kannel et al., 1979), triglycerides (Lippel et al., 1981), and the ratio of LDL to HDL (Kannel et al., 1979)

in the United States and other countries (Keys, 1970; Wilson, 1989). Recently, the search for factors that are related to elevated lipid levels has been broadened to include stress and emotional factors, primarily because known risk factors such as age, weight, blood pressure, diet, exercise, smoking, and alcohol intake do not account for all of the variance in elevated lipid levels (Dimsdale and Herd, 1982; Van Doornen and Orlebeke, 1982; Kannel and Eaker, 1986). Although variations in lipid levels are due partly to dietary factors, psychological factors such as stress and anger/hostility appear to be involved (Dimsdale and Herd, 1982). An early study by Jenkins et al (1969) showed that Type A behavior and its hostility dimensions were significantly related to serum cholesterol. Several recent studies show strong indications that emotional and personality factors, particularly anger/hostility, contribute to the rise in cholesterol levels among whites (Weidner et al., 1989; Lundberg et al., 1989; Waldstien et al., 1990) and blacks (Johnson et al., 1992).

Anger and Mortality From Heart Disease

Over the past decade a number of studies have actually shown that anger/hostility is an independent predictor of mortality from heart disease as well as overall mortality (Julius et al., 1986; Haynes et al., 1978, 1980; Shekelle et al., 1983; Barefoot et al., 1983; Grossarth-Maticek et al., 1980; 1985; for review see Johnson, 1990). Work conducted by the principal investigator and his colleagues has also shown that important interactions exist between anger conflict and hypertension such that the mortality risk for these individuals who are both hypertensive and have problems expressing their anger are approximately five times higher than individuals who don't have problems managing and expressing their anger (Julius et al., 1986).

Stress Reduction Therapy For Hypertension

It is quite well accepted that standard drug treatment for hypertension often causes adverse side effects that reduce quality of life (impairing physical, emotional, and social functioning, and cognitive processing) and is believed to be a causal factor in non-compliance with prescribed antihypertensive regimens among blacks and whites (Kaplan, 1990). Despite the fact that anti-hypertensive drug therapy is quite effective in reducing cardiovascular morbidity in blacks (HDFP Cooperative Group, 1979), it has been estimated that more than two-thirds of patients are non-compliant with their approach to the prevention and treatment of mild hypertension. The U.S. Joint National Committee on the Detection, Evaluation, and Treatment of High Blood Pressure (JNC, 1993) recommended the use of life-style modification therapies for the treatment of mild hypertensive patients based on findings from studies such as The Treatment of Mild Hypertension Research Group (1991 and 1992) and The Trial of Hypertension Prevention Collaborative Research Group (1992). The Joint National Committee on Hypertension (JNC V) recognized the need for prevention and management for mild (Stage 1) hypertension with interventions can also enhance the quality of life. In this regard, JNC V advised lifestyles therapies with interventions that can also enhance the quality of life. In this regard, JNC V advised lifestyle therapies for the initial treatment of Stage 1 hypertension or mild hypertension. JNC noted that only half of the studies on stress management showed significant BP effects. However, meta-analyses indicate that the effects of

meditation on BP are greater than the effects of other behavioral stress-reducing interventions.

Effects of Meditation on Blood Pressure, Cholesterol, and Quality of Life

Despite JNC recommendations that were made earlier in 1988 (JNC, 1988) and the strong evidence for the role of psychosocial stress in the evolution of hypertensive in blacks, there have been few controlled clinical trials of stress reduction therapies for the treatment of hypertension among blacks. In fact, the only controlled clinical trial of stress management procedures for hypertension in blacks is the study conducted by Robert Schneider and associates (Schneider, et al 1992). In brief, this study evaluated the effectiveness of one type of meditation, Transcendental Meditation (TM), progressive muscle relaxation training, as compared to usual non-drug care (diet and exercise) for managing mild hypertension among 80 elderly black adults. After 3 months of follow-up, TM and PMR groups showed significant blood pressure reduction compared to usual care. The significantly greater changes in the TM group (12/6 mmHg) were of the same order of magnitude as the average blood pressure reductions with drug therapy reported for most clinical trials of mild hypertension (Kaplan, 1990). Furthermore, both the TM group and the PMR group had over 90% compliance with treatment regimens. Whereas this study focused on older blacks (age 55 and older) and demonstrated significant reductions in both clinic and home blood pressure compared to usual care group, there is a need to determine whether stress reduction techniques will be effective in lowering the blood pressure for younger age blacks, and whether combining TM with stress reduction methods aimed at the management of anger/hostility would be more effective than TM alone in lowering blood pressure and improving the quality of life of people. There is also a need to learn about whether these stress-reduction therapies modify the response to both provocative laboratory stressors and real-life stressful events.

A large number of studies have examined the effectiveness of meditation in lowering blood pressure (Benson and Wallace, 1972; Blackwell et al., 1975; Pollack et al., 1977; Wallace et al., 1983). Kuchera et al (1986) reviewed and summarized the findings from 47 studies and reported that significant reductions in blood pressure can be obtained using meditation. Similar finding were reported in the review conducted by Schneider et al (1992). A study conducted by Cooper and Aygen (1978; 1979) also showed that meditation was effective in controlling elevated cholesterol.

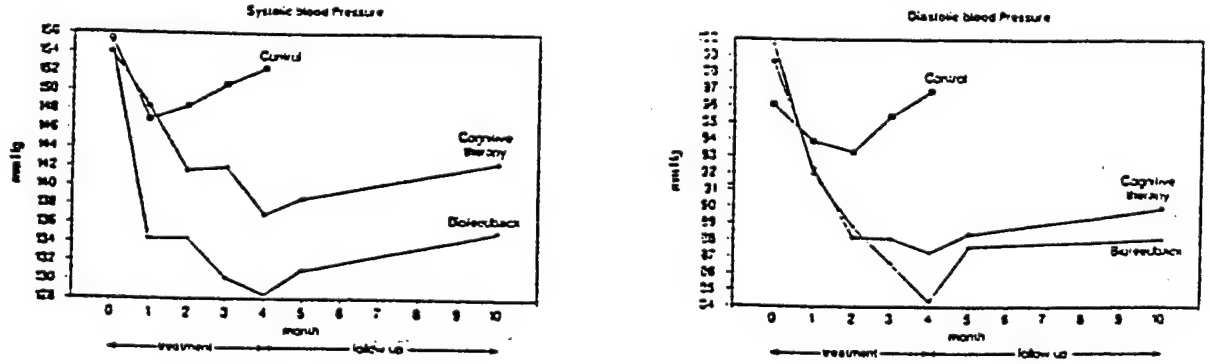
The effects of meditation on quality of life have been investigated in several studies that are summarized in a paper by Eppley et al. (1989). Individuals who regularly practiced meditation had substantial reductions in anxiety and the effects were twice that of other stress reduction techniques. Reductions in anger have been reported by Abrams and Siegel (1978), depression (Brooks and Scarano, 1985). The effects of meditation in reducing blood pressure and other cardiovascular risk factors (smoking, drinking, and cholesterol) have been reported by Orme-Johnson (1987) for a large group of people over five years. This study also showed substantial reduction in medical care utilization among individual who were meditating on a daily basis. An early study (Frew, 1974) also showed that meditation was significantly associated with greater adaptability at work as reflected by improved productivity, work performance and improved relationships with co-workers and supervisors. Improved performance on

intelligence related tasks has been recently reported for people who meditate regularly (Cranson et al., 1991) and meditation has been successfully used recently in the treatment and prevention of substance abuse (Aron and Aron, 1980; Clements, Krenner and Molk, 1988; Gelderloss et al., 1991). Greater marital adjustment has also been reported for meditators compared to non-meditating couples (Aron and Aron, 1982).

Anger Management And Hypertension

In a review of recent studies on arousal reducing treatments for hypertension (Ward, Swain and Chesney, 1987) it was revealed that for the average treated patient there was a large decrease in systolic and diastolic blood pressure than in the untreated patient. An impressive study was conducted by Chesney at al. (1987) in which they compared the effects of behavioral treatment in BP monitoring of blood pressure in 158 unmedicated people with essential monitoring of BP alone. This resulted in significant declines in blood pressure. A study by Achmon et al. (1989) examined the efficacy of a cognitive therapy for anger management, and heart rate biofeedback in reducing hypertension. Results from this investigation reveal that significant decreases in both systolic and diastolic blood pressure occurred for both behavioral treatments whereas no significant decrease in BP was found for the control conditions. To our knowledge, there have been no systematic investigation of whether between cognitive based anger management therapy and any other form of stress reduction therapies for black hypertensives or individuals with multiple risk factors for cardiovascular disease. Current work has been initiated by a National Institutes of Health funded project to Dr. Johnson which will address this issues among older blacks.

The blood pressure reductions (see figure below) for the cognitive anger management condition was 17/11 at the end of the intervention and 11/9 at the end of 6 months of follow-up. In all, 57% of the subjects who received Anger Management Therapy achieved a normal blood pressure (<140/90 mmHg) by the end of the treatment. These findings regarding the reduction of anger are very similar to work



reported by Alexander (1982) which show that two samples of people who regularly meditated (50% minorities who were participants in a 17 month longitudinal study of maximum security inmates demonstrate marked decreases in anger and anxiety compared to waiting list controls and participants in

four other treatment programs. In two other occupational settings Alexander et al. (1990) showed a wide range of quality of life improvements for employees who learned meditation compared to controls drawn from the same work sites over a 3 month period. These changes included alcohol consumption, and physiological activity during mental tasks, increased job productivity and satisfaction and increased work and personal relationships.

To date, there is a notable void in literature on the prevention of cardiovascular disease and health promotion programs (Magnus, 1991) among African-Americans. In the studies that do exist, evaluation components were either non-existent, still in progress, or crudely quantified.

Several studies (for reviews see Johnson, 1990; Williams, 1989) have revealed very strong independent associations between the way that anger/hostility is managed and expressed and mortality from cardiovascular disease. Finally, the results from focus groups conducted during the previous two summers with participants from the pilot study by Schneider et al. (1992) reveal that the black hypertensives believed that the meditation program was effective in reducing their blood pressures because it helped them "learn how to become less emotional, less prone to be upset," "produced situations where they were less angry and irritable about their life problems," "created a situation where they were able to think more clearly about the stresses in their lives and calm down before responding to them. These focus groups were conducted by the principal investigator of this proposal, and even through these data are qualitative in nature, it should be noted that the participants undergoing the meditation training received no formal information about whether meditation would have an impact on how they managed anger in their lives.

METHODS

This is a randomized, single-blind, controlled study of anger/hostility management combined with meditation verses a intensive educational program alone among 200 Black civilian women and 200 military women. All laboratory studies will be conducted while women are within the first 15 days of their menstrual cycle. Inclusion criteria. We are planning to recruit black, African-American, women, ages 18-30 years old, with diastolic BP 90-104 mmHg and who are >10% over ideal weight and who also have other risk factors for cardiovascular disease. Women who are receiving antihypertensive medications will not be enrolled in the study. These women will be randomized to either anger/hostility management & meditation or a lifestyle education group. Enrollment of 200-250 civilian women and 200-250 military women will likely be required to reach the goal of 400 women completing the study. The civilian women will be studies during years 1 and 2, while the military women will be studies during years 3 and 4. However, in the event that it is not possible to recruit the military women we will study another group of 200 civilian women who are all within the last 7 days of their menstrual cycle.

Exclusion criteria. Age>30 years; if on treatment for BP, inability to discontinue medications for any reason; fasting glucose > 140mg/dl, use of insulin or oral hypodermics; renal insufficiency; evidence of previous myocardial infarction by history of ECG; history of accelerated or malignant hypertension,

cerebrovascular accident (stroke); unstable angina, congestive heart failure; or evidence of major psychiatric illness, alcohol or drug abuse; pregnancy, or plans to become pregnant during the time of study.

Subjects will be recruited from health screenings conducted at black churches and through public advertisements. We plan to ascertain the following information from African American women ages 18-30 years old: Body fat distribution, fasting lipoprotein profile, 24-hour urine for dietary sodium and potassium, 3-day food diary, blood pressure/hypertension history, physical activity habits, alcohol consumption, cigarette smoking, job/family stress. job satisfaction, life stress questionnaires.

The diagnosis of hypertension in this study is based on blood pressure ascertained during the screening and clinic measurements. Casual (seated) BP will be obtained in triplicate on the right arm supported at heart level after the subject has rested for five minutes. The three readings will be averaged, and phase 5 Korotkoff will define diastolic BP. Subjects will be instructed not to practice meditation immediately before or during the time their clinic BP is recorded. Only volunteers with diastolic BPs at the screening and follow-up clinic visits consistently in the 90-104 mmHg range and systolic BP's <180 mmHg and who are >10% over ideal weight are eligible.

The single blind will be maintained by having research staff obtain the BP and physiological data who are unaware of the subjects intervention status. The two groups will receive equal amounts of professional contact time. The effects of the two interventions on measures of anger, sympathetic drive neurovascular tone, cardiovascular reactivity and the risk factor cluster will be evaluated in black women with high and low levels of anger/hostility. Patients who withdraw from the study will be replaced. As with the civilian women, only military women volunteers with diastolic BPs consistently in the 90-104 mmHg range and systolic BP's <180 mmHg and who are >10% over ideal weight are eligible. All participants must also have other risk factors for cardiovascular disease to be eligible for the study.

Intervention and Control Group

Each of the active treatments will be introduced in ways that encourage some degree of expectancy and benefits for the prevention of disease and promotion of health. Prior to the enrollment of subjects in the intervention, subjects will be questioned about their expectations regarding the treatment on their blood pressure as well as how they expect the treatments to improve their overall physical and emotional health.

The anger/hostility & meditation and cardiovascular risk education interventions will be taught with similar formats, amount of instructional times, professional attention from the instructor and daily practice time. The general format of instruction in the active treatments (anger/hostility management & meditation) will be modeled after the standard meditation training course. This includes an introductory lecture meeting which is done in group format to discuss benefits and mechanisms of the technique, a brief personal interview, a session of personal instruction, and follow-up in group meetings. These initial steps will take place over 2 consecutive days and last about one hour per day. At the end of this period, the groups will meet once a week for roughly one hour and a half for the next 8 weeks (2 months). This will

constitute the active part of the intervention and following this phase all of the groups will be entered into a follow-up phase with meetings every month with their respective instructors. Members in all groups will be instructed not to reveal the identities or details of their practice to other participants or the data collection staff during the course of the study. The participants will not be aware of the treatment group that is hypothesized to be more active than the other. For this reason and because data collection staff will also be blind to treatment status, the study may be considered-blind.

Anger Management and Meditation: The meditation technique is a simple mental procedure, practiced twice a day for 20 minutes while sitting with the eyes closed. During the technique the ordinary thinking process settles down and a distinctive psychophysiological state of "restful alertness" appears to be gained (Wallace, 1970). A recent quantitative meta-analysis" indicates that meditation, in comparison to resting with eyes closed, produces twice the statistical effect on measures of breath rate reduction, plasma lactate, and basal galvanic skin resistance. Previous studies on meditation practitioners have reported lower cardiovascular reactivity and decreased adrenergic receptor sensitivity (Mills et al., 1987), enhanced autonomic recovery to laboratory stressors (Goldman and Schwartz, 1976), and decreased plasma cortisol (Jevning et al., 1978). Indicators of heightened alertness during meditation further distinguish it from relaxation (reviewed in Alexander et al., 1990). These include acute increases in alpha EEG coherence across cortical areas (Dillbeck and Bronson, 1981) and enhanced brain blood flow (Jevning et al., 1978).

Novaco

Anger Manage

During the next 8-weeks the subjects will learn using methods of cognitive therapy that are based on the work of Novaco (1975, 1977, 1980) and on the application of "stress inoculation" to anger (Meichenbaun, 1985; Novaco 1981, 1978, 1991, 1992). Scheduled exercise and role playing are included in the therapy in order to improve both expression of anger emotions and assertive behaviors. The group treatment phase will consist of weekly sessions that focus on lowering the level of "general anger" and increasing the overall expression of anger. The participants will undergo initial treatment sessions that focus on "cognitive preparation." In this phase the person is introduced to the rationale of treatment approach; has to keep a diary of the frequency, intensity and duration of anger episodes as well as to identify situations that trigger anger, and then to begin to learn how to distinguish anger from hostility and aggression. During the next major phase of the therapy, referred to as "skills acquisition," which occurs on the second or third session, the person is taught relaxation skills and how to maintain a sense of humor as a response to anger. Respondents are taught how to dissect a provocation experience into its sequences of stages that consist primarily of: (a) preparation of provocations, (b) dealing with the confrontation and its impact, (c) coping with physiological and emotional arousal through relaxation and graded task assignments (i.e., using shaping procedures of small sequential steps that lead to the desired goal. Basically, the patients develop anger hierarchy --from least to most provocative events--and learns how to deal with events with a minimum of stress), and (d) coping with subsequent reflections about the provocation by altering self statements about the event. Subjects will be instructed how to practice using the cognitive anger management techniques with exposure to regulated doses anger provoking

TM ↓ BP ↓ Lipids? Chol ↓ Cortisol

circumstances in order to facilitate learning how effectively cope with arousal anger feelings. The effects of cognitive behavioral techniques for managing anger have been well documented in cases concerning child and spouse abuse, and the techniques have been used with other individuals who find themselves in situations where they are often provoked by other people (Novaco, 1975, 1992).

Cardiovascular Risk Factor Education (CRFE): The participants in this group will receive instruction for modifying the major risk factors with conventional behavioral approaches. Subjects will receive the same number of sessions as participants in the active intervention conditions. They will learn about the importance of diet, salt, weight control or management, exercise and the effects of these factors on controlling blood pressure. The group sessions will include information on smoking cessation and promotion of physical activity. The subjects will also cover the topic of stress in a didactic format, but they will not be given instructions in a specific stress reduction or relaxation technique. The group sessions will be led by the health educator who has extensive experience in conducting health education courses. Instructions in this group include the following:

1. Lose weight if overweight (This refers to individuals who are more than 10% over ideal body weight)
2. Limit alcohol intake to no more than 1 ounce of ethanol per day (24 ounces of beer, 8 ounces of wine, or 2 ounces of 100 proof whiskey.)
3. Exercise (aerobic) regularly, such as walking more than 20 minutes three times a week.
4. Reduce sodium intake to less than 100mmol per day (<2.3 grams of sodium or <5 grams of sodium chloride).
5. Maintain adequate dietary potassium (>70 mmol/d), calcium (>20 mmol/d), and magnesium (>12 mmol/d) intake.
6. Stop smoking and reduce dietary saturated fat and cholesterol intake for overall cardiovascular health. Reducing saturated fat intake (< 10% of total calories) and cholesterol intake (<300 mg/day) which are important for control of weight and Type II diabetes. (These recommendations will also be summarized on the sheet handed out to all subject participants at the beginning of the study as part of usual care.

The participants in the CRFE control group will attend weekly one-hour instructional meetings during the first 8 weeks of the intervention period and then one-hour meeting per month thereafter for the duration of the follow-up period. By participating in this intervention, subjects will receive useful non-pharmacologic instruction for the self-treatment of their hypertension. The well-organized structure of the program assures that the subjects interest and participation is maintained over the study. However, due to the less intensive nature of the intervention, the resulting reduction in blood pressure is predicted to relatively modest.

Cardiovascular Stress Reactivity. All civilian participants enrolled in the intervention phase of the study will undergo the following tests prior to the intervention groups, at the end of the 8 week intervention and at the 1 and 3 month follow-up. The reactivity protocol has been used previously by the

principal investigator (Johnson et al., 1992). The tests selected represent a range of autonomic stressors from relatively selective B-adrenergic stressors (mental arithmetic) to relatively selective a-adrenergic stressors (forehead cold tests). Subjects systemic hemodynamic (BP, heart rate [HR], cardiac output [CO]), and calculated total systemic vascular resistance [TSR] response to the various stressors will be obtained at 2 minute intervals in those tests or recovery periods lasting more than 4 minutes and every minute during shorter interventions. Cardiac output. Stroke volume (SV, ml/beat) is estimated non-invasively by impedance cardiograph using the Minnesota impedance cardiograph, Model 304B; Surcom Inc., Minneapolis, MN. Absolute stroke volumes as well as changes in stroke volumes obtained using the impedance technique correlate will with values obtained by dry or thermal dilution. **Laboratory stress studies of military women will be restricted to the assessment of blood pressure and heart rate responses. However, they will be exposed to the same stressors as the civilian women and complete the same battery of psychosocial, lifestyle, and health behavior questionnaires.**

a. Resting baseline. Subjects listen to quiet music for 20 minutes.
b. Mental arithmetic (10 minutes). Subjects begin with serial 7's at the number 1079, and count backward aloud as quickly as possible. If this completed prior to the allotted time, they will do the serial 13's. As an incentive, participants will receive a $5.00 bonus for completing the 7's and begin the 13's within the time provided.
c. Mental arithmetic recovery (10 minutes). Subjects will be told to relax during this period
d. Hand grip recovery (2 minutes). Subjects will be required to maintain grip at one third of maximum for 2 minutes as determined from an average of 3 maximum hand grip attempts.
e. Hand grips recovery (4 minutes). Subjects will be told to relax.
f. Cold pressor hand test (1.5 minutes). Subjects will be required t immerse their right hand into ice for 90 seconds (less selective for a-adernergic response than the forehead test).
g. Cold pressor hand recovery (4 minutes). Subjects will be told to relax.
h. Cold pressor forehead test (1.5 minutes). A plastic bag containing crushed ice and water is applied to the subject's forehead for 90 seconds.
i. Cold pressor forehead recovery (4 minutes). Subjects will be told to relax during this period.
j. Structured Anger Assessment Interview (SAAI, see below) 18-24 minutes. The SAAI is a 24 question challenge interview that measures how people cope with feelings of anger and irritation challenge interview that measures how people cope with feelings of anger and irritation related to current stressful events. Although the interview challenges the subjects responses to certain interview questions, the interview is never hostile (Johnson and Greene, 1992).
k. SAAI recovery (10 minutes). Subjects will be told to relax.

Structured Anger Assessment Interview (SAAI). The subjects emotional states (anxiety, anger)

will be assessed prior to the start of the reactivity test and at the end of the the SAAI recovery period. Subjects are asked to rank the most successful areas of their lives including relationships with spouse or significant other, personal finances, job, school, personal health, sex life, family, etc. The interviewer encourages subjects in a friendly way to provide details about the nature of the stressors. The SAAI will be audio-taped and scored for both verbal content and behavioral manifestations of anger and hostility. Each question on the SAAI is assessed for the specific content of the responses, while the behavioral assessment is based upon the general stylistics and vocal mannerisms of the subject as they answer the questions. Since many questions are taken from the self-report questionnaire measures of anger, the consistency of responses across the two assessment methods can be determined. Preliminary validity data from the SAAI (Johnson and Greene, 1992) suggest that the self-report of Speilberger Trait Anger correlates with the SAAI Angry Reaction-Frequency subscale across samples. Similarly, the Spielberger Anger-Out Verbal and Anger-Out Object Displacement scores. SAAI Disabling Anger and Problems with Anger Control correlated with Loud and Explosive Speech. Inter-rater and test-retest reliability were shown for the verbal-behavioral ratings.

After completion of the cardiovascular reactivity session, forearm plethysmograpy will be performed using a mercury-in-silastic strain gauge (D.E. Hokanson, Inc., Issaquah, Wash.) to measure minimal forearm vascular resistance. This procedure requires the subjects to perform contractions of the forearm muscles while an inflated tourniquet interrupts the forearm blood flow (mL/min/dL of forearm volume) for 10 minutes. The cuff will then be released and the flow (maximum forearm blood flow) will be measured during the ensuing post-ischemic perfusion. During such maximal dilation, the arterioles are entirely relaxed, and the resistance to flow reflects the structural properties of the vessel; a thicker wall of a hypertrophic vessel impinges on the lumen and causes higher resistance (Egan and Julius, 1985; Johnson 1990; Johnson et al., 1992 Egan et al., 1988; Egan, 1992). Minimum forearm vascular resistance will be calculated as mean arterial pressure divided by maximum forearm blood flow. The maximum flow will be determined from the mean of the six highest flow curves obtained in the 60 to 90 seconds following the ischemic period. After the plethysmography measurements are obtained, the research assistant will prepare the subject for the ambulatory BP session.

Ambulatory BP monitoring (ABPM). ABPM data improve the prediction of morbidity among hypertensive patients. Subjects will be fitted with a Space Lab 90207 monitor. The accuracy of the instrument will be verified against a mercury manometer using a T-tube. Readings will be taken every 30 minutes during the day (0600-2300) and hourly during the night. Subjects will be instructed to follow their normal daily routine and to complete a diary card which describes their posture, mood, and level of stress for each daytime reading. The BP monitor will be returned to the clinic the next morning and the stored data will be retrieved via interface to an IBM PC. Each reading will be automatically validated by the software program using established criteria.

DESCRIPTION OF MEASURES OBTAINED FROM PARTICIPANTS

Overweight is defined as body mass index (BMI) 25-27 kg/m2 and obesity is defined as BMI >27-40 kg/m2. Subjects with severe obesity (BMI>40 kg/m2) are excluded. Defining obesity by BMI does not distinguish between overweight and overfat. Thus, body fat is estimated. **Body fat distribution** will be assessed with skinfolds and waist-to-hip ratio (WHR). A thicker SS skinfold and a higher SS/TC skinfold ratio have been correlated with cardiovascular risk factors including hypertension and diabetes. The WHRs are associated with insulin resistance, diabetes mellitus (NIDDM), hypertension and diabetes. Greater WHRs are associated with insulin resistance, diabetes mellitus (NIDDM), hypertension, and coronary heart disease.

Plasma catecholamines, plasma renin activity, and plasma aldosterone concentration, will be measured in the Basic Medical Sciences core Laboratories at Morehouse School of Medicine (MSM) under the direction of Dr. Sandra Harris-Hooker.

Dyslipidemias. A fasting lipoprotein profile including total cholesterol, triglycerides and HDL-cholesterol is obtained and LDL-cholesterol is calculated using the Friedewald equation. Hypercholesterolemia is defined according to National Cholesterol Education Program guidelines. Since many hypertensive patients have at least one of the risk factor (e.g., obesity,cigarette smoking), total cholesterol>200 mg/da and LDL-cholesterol > 130 mg/dl are abnormal. Based on evidence from Framingham and other sources, triglycerides > 150 mg/dl, particularly in association with HDL-C <40 for women and <35 mg/dl for men are abnormal. These measures will be determined at MSM laboratories under the direction of Dr. Sandra Harris-Hooker.

Dietary Na+ and K+ intake. 24-hour urines for Na, K, creatinine will be obtained on every patient. These measures will de determined at the MSM laboratories under the direction of Dr. Sandra Harris-Hooker. A 3-day food diary will be obtained for each subject to measure sodium, potassium, calcium, magnesium, total calories and percentage of fat in the diet. We will use the Nutritionist IV computer analysis system under the supervision of our Nutritionist.

Structural cardiovascular changes. The forearm vascular resistance following 10 minutes of ischemic forearm exercise provides an index of structural arteriolar cross-sectional area.

Physical activity, alcohol consumption, and cigarette smoking are variables which the lifestyle education program will attempt to positively change. Compliance with these instructions may differ between the two groups in this study. If true, then these changes could confirm interpretation of the specific and more direct effects of the intervention on BP, lipids, glucose, insulin, neurovascular regulation, and psychophysiological reactivity. Therefore, these potentially confounding variables will be assessed with the questionnaire modeled after the MRFIT instrument.

Women's Health Questionnaire. This questionnaires will measure health problems and concerns that are specific to women such as menstrual cycle irregularities, history of sexual transmitted diseases, history of breast and cervical cancer and pregnancy problems.

Compliance and expectancy. Compliance beginning from the initiation of the anger/hostility

management & meditation and education will be defined according to methods suggested by Jacobs and Chesney. First, subjects will record their daily practice of meditation on a specially constructed log card for the week preceding each ambulatory BP monitoring. This card is the size of a pocket calculator and has a place for checking a.m. and p.m. practice times. An indirect but objective indicator of compliance is the attendance record at educational and follow-up meetings. Attendance records will be kept by the anger/management & meditation and lifestyle instructors.

The National Survey of Black Americans (NSBA) questionnaire: The NSBA questionnaires are used as part of an ongoing group of studies conducted by the Program for Research on Black Americans at the Institute for Social Research at the University of Michigan. The NSBA questionnaire includes a host of information concerning the lifestyle and psychosocial functioning of blacks. Data regarding social support,negative life events, religious involvement, group identity, stress and coping, health care utilization patterns, self-report of diagnosed health problems and symptoms, work and family stress, job satisfaction and job performance, and other areas of life are included in the questionnaires. Information pertaining to the perception of racism and the impact of racism on self confidence, self esteem and well-being are available from the NSBA questionnaire. The PI is very familiar with the NSBA questionnaire and has published a few papers (Johnson and Broman ,1987; Broman and Johnson, 1988; Johnson, 1989) on the links between psychosocial factors and health based on these data. Reliability and validity studies have been conducted for all of the information included in the NSBA questionnaire and detail information on the sampling and interviewing procedures can be found in Jackson et al., 1982; Johnson and Broman, 1987).

The experience and expression of anger and anxiety: We will use the State Trait Personality Inventory to measure the intensity of anger and anxiety at the time of testing (State) and general measure of the disposition (Trait) to frequently experience feelings of anger and anxiety will be determined with this questionnaire that was developed by Spielberger and his associates (Spielberger et al., 1987; Spielberger, Johnson et al., 1985; Johnson, Spielberger et al., 1978a; Johnson, Spielberger et al., 1987b). The expression of anger will be measured using the anger expression scale which was also developed by Spielberger and associates to assess the frequency that anger has expressed behaviorally (anger out) suppressed (anger in), are controlled (anger-reflection/control). Another measure of anger assesses the intensity of anger feelings includes an overall intensity scale and three subscales for determining the intensity of anger reactions to "time pressure," "evaluative and threatening situations," and "family and job stress." The scale was developed by the PI (Johnson et al., 1987a, 1987b; Johnson, 1989).

Rationality/emotional defensiveness (R/ED) and need for harmony (N/H) scales: We will use these two brief self-report questionnaires that asses rational, non-emotional reactions in interpersonal relationships. These items were derived from Grossarth-Maticek's (Grossarth-Maticek, 1985; Grossarth-Maticek et al., 1985) prospective epidemiological study.

Hostility: This attitude and personality trait will be measured with the Cook and Medley (1954) hostility questionnaire which has been found to be predictive of heart disease and cardiovascular risk factors for

heart disease (see Williams, 1989).

1, 6 and 12 Month Post-Intervention Follow-Up: Women who complete the intervention will have a follow-up evaluation of their blood pressure, cardiovascular responses to stress, 24-hour ambulatory blood pressure assessment, lipids, 3-day food diary for assessing total calories, percentage of fat, sodium, potassium, calcium, and magnesium. They will also complete the questionnaires to determining interpersonal, family and job stress, job performance and the health behavior questionnaire.

ANALYSES

We will connect to the CDC main frame via high speed modem which makes available all of the major statistical software packages and data management packages available at the CDC. There is no fee for access to the CDC's main frame and statistical management packages because of a cooperative agreement that the CDC has with Morehouse College. Other statistical support is available from other staff at the CDC. Dr. Johnson also holds a joint appointment with the School of Public Health at Emory University. The faculty at the School of Public Health have access to biostatisticians for their projects. The data collected from the screening will be organized by the Data Manager/Analyst to examine the interrelationship between psychosocial factors and cardiovascular risk factors. The hypotheses for the baseline measures will be addressed using correlational, multiple regression analyses, and analysis-of-covariance. An alternative way of approaching this questions is to form high vs low anger/hostility classifications from the examination of the distribution of scores on the Trait-Anger and Cook-Medley Hostility Questionnaires. There are normative data for both of these measures and high anger/hostility scores can be designated as those above the 75th percentile for the population. Therefore, high vs low anger/hostility groups can be defined to determine the extent that anger/hostility is related to cardiovascular risk factors and psychosocial factors as specified in the specific aims. In this case, discriminative function analyses can be used to address the hypotheses.

The analyses to examine the effectiveness of the interventions will consist of analyses of co-variance. To determine the effectiveness of the interventions across we will use repeated measures analyses of covariance. Dependent measures will consist of the risk-factor cluster scores that will be computed by assigning a score of one for each of the following factors: Mild hypertension, hyperinsulnemia, overweight, dyslipidemia, high anger/hostility. Therefore, a maximum risk-factor cluster score is 5. Other variables such as smoking, drinking, exercise habits will be used as covariates.

Reduction of cardiovascular responses to laboratory stress will be evaluated using multiple-analysis of co-variance with the covariates being the baseline measures preceding the lab stressors. The within group factors will be pre-or post-treatment levels while the between group factors will be the two treatment conditions. The stress reactivity data could also be analyzed using the resting baseline periods to calculate delta charge scores and submitting these to appropriate analyses. Data derived from the anger interview will be used to determine the effects of the interventions on reducing emotional reactivity to stress. The emotional reactivity measures will consists of measures of anger, anxiety, depression collected

prior to the stress testing. Other data derived from the anger interview which will focus on the subjects response styles will be analyzed by multiple-analysis of covariance.

The effectiveness of the interventions in reducing the blood pressure response to natural stresses (outside of the laboratory) will be determined from the assessment of the 24-hour ambulatory blood pressure readings. Information from the computerized behavioral diary records will be integrated with the blood pressure readings. The treatment groups effects can be analyzed using analysis of variance and co-variance techniques.The changes on the battery of psychological, interpersonal, family/job stress, and lifestyle measures will be assessed using repeated measures multiple-analysis of covariance.

The longitudinal or follow-up data will be analyzed using regression and path analytic techniques to address questions about changes in health and stress for participants in the intervention vs control group. The data will also be submitted to other analyses that address questions concerning whether the intervention was equally effective for civilian vs military women.

PRINCIPAL INVESTIGATOR QUALIFICATIONS

Ernest H. Johnson is a 1984 PhD., in Clinical/Health Psychology from the University of South Florida in Tampa Florida. Dr. Johnson received special training in hypertension research from the Division of Hypertension at the University of Michigan Medical Center from 1985-1989 where he held an appointment of Assistant Professor of Internal Medicine. He has recently completed a 5-year term on the Behavioral Medicine Research Grants Review Section of the National, Heart, Lung and Blood Institute of the National Institutes of Health. He has held appointment as Associate Professor at the University of Houston and University of Miami. He is currently Professor and Director of Behavioral Medicine Research at the Department of Family Medicine at Morehouse School of Medicine. Dr. Johnson recently (1992) completed an edited book, Personality, Elevated Blood Pressure and Essential Hypertension, which includes contributions from several of the leading experts in the world.

Dr. Johnson will have ultimate responsibility for all scientific aspects of the study. He will oversee all project activities, which will include developing the laboratory protocols: training research assistants; implementing the research design; collecting, managing the coding, analysis and interpretation of data, and writing reports for publications and presentations at professional meetings. He will supervise all project staff and their scientific, clinical, and support services role, and will also supervise the quality control aspects of the intervention and a data collection condition during the intervention and stress reactivities sessions. Technical reports of the data will be prepared every six months to ensure quality control. Dr. Johnson has gained considerable experience as a research investigator as evidenced by the funded research he has been involved and his publication recorded. He is very familiar with the protocol of Meditation training and the cognitively based anger/hostility management treatment protocol; has considerable expertise in all laboratory aspects of the cardiovascular reactivity studies, and he is very familiar with the process of organizing and directing large scales studies. For example, Dr. Johnson was the project director and co-principal investigator for a rather large study of young adults (N=800) in the city of

Tecumseh, Michigan, during his stay at the division of Hypertension at the University of Michigan Medical Center. Dr. Johnson was in charge of all operational day-to-day aspects of this study of physiological and behavioral process predictive of future hypertension which required him to supervise a staff of 3 physicians and 10 technicians. He also worked on the National Survey of Black Americans while at the University of Michigan and has managed large data collection efforts to examine interrelationships between psychosocial factors, health behaviors, and HIV risk behaviors.

Dr. Johnson's effort will be 30% for years 1-3 and 50% during the fourth year.

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